



U.S. Department of Justice

United States Attorney  
District of New Jersey

970 Broad Street, Suite 700  
Newark, NJ 07102

973/645-2700

JM/SS/PL AGR  
2008R00799

January 3, 2013

John N. Nassikas, Esq.  
Baruch Weiss, Esq.  
Laura Lester, Esq.  
Arnold & Porter LLP  
555 Twelfth Street, NW  
Washington, DC 20004-1206

Re: Plea Agreement with Par Pharmaceutical Companies, Inc.

Dear Mr. Nassikas:

This letter sets forth the plea agreement between your client, Par Pharmaceutical Companies, Inc. ("Par") and the United States Attorney for the District of New Jersey ("this Office").

Charge

Conditioned on the understandings specified below, this Office will accept a guilty plea from Par to a one-count Information, which charges Par with introducing or delivering a misbranded drug into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1). If Par enters a guilty plea and a judgment of conviction is entered that is consistent with terms of the agreed disposition included in this plea agreement under Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, and if Par otherwise fully complies with all of the terms of this agreement, this Office will not initiate any further criminal charges against Par or any of its subsidiaries, including Par Pharmaceutical, Inc., with respect to its sales, marketing and promotion of Megace® ES from July 2005 to the present. However, in the event that a guilty plea in this matter is not entered for any reason or the judgment of conviction entered as a result of this guilty plea does not remain in full force and effect, Par agrees that any dismissed charges and any other charges that were not time-barred by the applicable statute of limitations on the date the tolling agreements were executed by the parties may be commenced against Par, notwithstanding the expiration of the limitations period after the date of the tolling agreements and/or the date Par signs the agreement.

### Sentencing

The violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1) to which Par agrees to plead guilty carries a statutory maximum term of probation of 5 years, and a statutory maximum fine equal to the greatest of: (1) \$200,000; (2) twice the gross amount of any pecuniary gain that any persons derived from the offense; or (3) twice the gross amount of any pecuniary loss sustained by any victims of the offense. See 18 U.S.C. §§ 3561(c)(2), 3571(c)(5), 3571(d). Fines imposed by the sentencing judge may be subject to the payment of interest.

Further, in addition to imposing any other penalty on Par, the sentencing judge: (1) will order Par to pay an assessment of \$125 pursuant to 18 U.S.C. § 3013, which assessment must be paid by the date of sentencing; and (2) may order Par to pay restitution pursuant to 18 U.S.C. § 3563.

The parties agree that while the fine provisions of the United States Sentencing Guidelines ("U.S.S.G.") do not apply to organizational defendants for misdemeanor violations of the Federal Food, Drug, and Cosmetic Act, see U.S.S.G. § 8C2.1, the fine agreed upon by the parties is consistent with the U.S.S.G. and takes into account Par's conduct under 18 U.S.C. § 3553 and 3572, as follows:

- (1) The parties agree that the base fine is \$11,000,000, in that such amount was the reasonably estimated pecuniary gain to Par from the offense, see U.S.S.G. §§ 8C2.3, 8C2.4(a);
- (2) Pursuant to U.S.S.G. § 8C2.5, the culpability score is seven (7), which is determined as follows:
  - (i) base culpability score of five (5) pursuant to U.S.S.G. § 8C2.5(a);
  - (ii) add three (3) points pursuant to U.S.S.G. § 8C2.5(b)(3)(A) because the organization had 200 or more employees, and an individual within high-level personnel of the organization participated in, condoned, or was willfully ignorant of the offense; and
  - (iii) deduct one point for Par's acceptance of responsibility for its criminal conduct pursuant to U.S.S.G. § 8C2.5(g)(3).

- (3) Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of seven (7) is 1.4 to 2.8; and
- (4) Therefore, the advisory Guidelines Fine Range is \$15,400,000 to \$30,800,000.

This Office and Par agree that, pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), the appropriate disposition of the case is as follows, and will result in the imposition of a reasonable sentence that is sufficient, but not greater than necessary, taking into consideration all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572:

- (1) Par shall pay a criminal fine in the amount of \$18,000,000 within seven (7) days after sentencing;
- (2) Par shall pay a special assessment of \$125;
- (3) Par shall be subject to pay forfeiture in the amount of \$4,500,000, and such amount shall be paid prior to the time of the plea hearing;
- (4) The United States agrees that it will not seek a separate restitution order as to Par as part of the resolution of the charge in the Information. The United States and Par agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a restitution order outweighs the need to provide restitution to non-governmental victims, if any, in this case; and
- (5) The United States further agrees that it will not seek a term of probation in light of: (i) the remedial measures undertaken by Par to date; (ii) the enhanced corporate rehabilitative compliance measures and certifications agreed to by Par as attached hereto as Exhibit 1; and (iii) the Corporate Integrity Agreement entered into between Par and the Office of the Inspector General of the Department of Health and Human Services, attached hereto as Exhibit 2.

Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), this Office and Par agree that no other sentence or

fine is appropriate, beside those set forth above. If the Court accepts this plea agreement, Par must be sentenced accordingly. If the Court rejects any aspect of this plea agreement or fails to impose a sentence consistent herewith, this agreement shall be null and void at the option of either the United States or Par, except that Par expressly waives, and agrees that it will not interpose, any defense to any charges brought against Par which Par might otherwise have under the Constitution for pre-indictment delay, any statute of limitations, or the Speedy Trial Act. If Par fails to pay any amounts within the time frames specified in this plea agreement, this agreement shall be null and void at the sole option of the United States. See 18 U.S.C. § 3614.

#### Other Litigations

Par agrees that it will, before the time of entry of the guilty plea in this matter, at the Government's request, file a motion to strike those portions of pages 10 and 11 of Par's March 23, 2012 submission in Par Pharmaceutical, Inc. v. United States of America, et al., 11-CV-1820 (RC) (JMF), identifying specific conversations with government attorneys. In withdrawing these portions, Par will state that it does not concede that the discussions included are protected or privileged, or that their inclusion in Par's briefs constitutes any violation of a rule, regulation, or statute (including Fed. R. Evid. 408 and 410).

Par also agrees that it will, before the time of entry of the guilty plea in this matter, execute and provide to the Government executed copies of a joint stipulation of dismissal with prejudice for each of the actions entitled Par Pharmaceutical, Inc. v. United States of America, et al., 11-CV-1820 (RC) (JMF), and In re Grand Jury Matter, 11-2679 (3d Cir.). Par further agrees that it will file these stipulations of dismissal immediately upon the completion of sentencing in this matter. If Par fails to file those stipulations of dismissal immediately upon the completion of sentencing, the Government is hereby authorized to file those joint stipulations of dismissal on Par's behalf.

#### Rights of the Parties Regarding Sentencing

Except as otherwise provided in this agreement, all parties to this agreement reserve their rights to correct any misstatements relating to the sentencing proceedings, and to provide the sentencing judge and the United States Probation Office all law and information relevant to sentencing, favorable or otherwise. In addition, the parties may inform the sentencing

judge and the United States Probation Office of: (1) this agreement; and (2) the full nature and extent of Par's activities and relevant conduct with respect to this case.

Waiver of Appeal and Post-Sentencing Rights

Par knowingly and voluntarily waives the right to file any appeal, any collateral attack, or any other writ or motion, including but not limited to an appeal under 18 U.S.C. § 3742 or a motion under 28 U.S.C. § 2255, which challenges the conviction or sentence imposed by the Court if the plea is accepted and the sentence is imposed in accordance with the terms of this agreement.

This Office will not file any appeal, motion or writ which challenges the conviction or sentence imposed by the Court if that sentence is imposed in accordance with the terms of this agreement. Furthermore, if the Court accepts the terms of this plea agreement, both parties waive the right to file an appeal, collateral attack, writ, or motion claiming that the Court erred in doing so.

Both parties reserve the right to oppose or move to dismiss any appeal, collateral attack, writ, or motion barred by the preceding paragraphs.

Forfeiture

Par agrees that as part of its acceptance of responsibility, Par will forfeit to the United States assets subject to forfeiture pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c). Par admits that the value of the quantities of Megace® ES that were misbranded and distributed in violation of 21 U.S.C. § 331 totaled approximately \$4,500,000 in United States currency.

Par acknowledges and agrees that the quantities of Megace® ES which were misbranded and distributed in violation of 21 U.S.C. § 331 cannot be located upon the exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, Par agrees that the United States is entitled to forfeit as "substitute assets" any other assets of Par up to the value of the now-missing directly forfeitable assets.

Par agrees that, before the time it enters a plea of guilty pursuant to this agreement, it shall remit the amount of

\$4,500,000 in United States currency to the United States Marshals Service. Payment shall be made by certified or bank check payable to the United States Marshals Service. Before it enters a plea of guilty pursuant to this agreement, Par shall cause said check to be hand-delivered to the Asset Forfeiture and Money Laundering Unit, United States Attorney's Office, District of New Jersey, 970 Broad Street, Newark, New Jersey 07102. Par and the United States agree that this payment shall satisfy any and all forfeiture obligations that Par may have as a result of its guilty plea.

Forfeiture of substitute assets shall not be deemed an alteration of Par's sentence. The forfeitures set forth herein shall not satisfy or offset any fine, restitution, cost of imprisonment, or other penalty imposed upon Par, nor shall the forfeiture be used to offset Par's tax liability or any other debt owed to the United States.

Par agrees to consent to the entry of an order of forfeiture for \$4,500,000 in United States currency, and waives the requirements of Federal Rules of Criminal Procedure 32.2 and 43(a) regarding notice of the forfeiture in the charging instrument, entry of a preliminary order of forfeiture, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment. Par acknowledges that it understands that the forfeiture of assets is part of the sentence that may be imposed in this case and waives any failure by the Court to advise it of this, pursuant to Federal Rule of Criminal Procedure 11(b)(1)(J), at the time the guilty plea is accepted.

In addition to all other waivers or releases set forth in this agreement, Par hereby waives any and all claims arising from or relating to the forfeiture set forth in this section, including, without limitation, any claims arising under the Double Jeopardy Clause of the Fifth Amendment, or the Excessive Fines Clause of the Eighth Amendment to the United States Constitution, or any other provision of state or federal law. The United States District Court for the District of New Jersey shall retain jurisdiction to enforce the provisions of this section.

#### Other Provisions

This agreement is limited to the United States Attorney's Office for the District of New Jersey and cannot bind other federal, state, or local authorities. However, this Office will bring this agreement to the attention of other prosecuting offices, if requested to do so.



This agreement was reached without regard to any civil or administrative matters that may be pending or commenced in the future against Par. This plea agreement does not prohibit the United States, any agency thereof (including the Internal Revenue Service), or any third party from initiating or prosecuting any civil or administrative proceeding against Par.

Par agrees that it is authorized to enter into this agreement, that it has authorized the undersigned corporate representative, Paul V. Campanelli, Par's Chief Executive Officer, to take this action, and that all corporate formalities for such authorization have been observed. Par further agrees that the plea of guilty will be entered by Paul V. Campanelli on behalf of Par, and that Paul V. Campanelli is authorized to enter a plea of guilty on Par's behalf. By entering this guilty plea, Par hereby waives all objections to the form of the charging document and admits that it is in fact guilty of the offense charged in the Information. Par further agrees that if it sells all or substantially all of its business operations as they exist as of the date of this agreement to a single purchaser or group of affiliated purchasers during the term of the agreement as set forth in Exhibit 1, or merges with a third party in a transaction in which Par is not the surviving entity, Par shall include in any contract for such sale or merger a provision binding the purchaser, successor, or surviving entity to continue to comply with Par's obligations in this agreement, including Exhibit 1.

#### Corporate Authorization

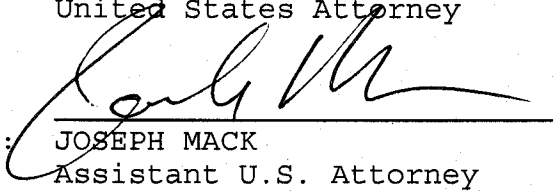
Par's corporate acknowledgment of: (a) this agreement; and (b) the corporate resolution authorizing entry into and execution of this agreement, is attached as Exhibit 3. Par has provided to the United States a certified copy of a resolution of the governing body of Par, affirming that it has authority to enter into this agreement and has (1) reviewed this plea agreement and the Information in this case; (2) consulted with legal counsel in this matter; (3) authorized execution of this agreement; (4) authorized Par to plead guilty to the Information; and (5) authorized Paul V. Campanelli to execute this agreement and all other documents necessary to carry out the provisions of this agreement. A copy of this resolution is attached hereto as Exhibit 4. Par further agrees that Paul V. Campanelli shall appear on behalf of Par, provide an accurate and truthful allocation at the plea hearing, enter the guilty plea, and appear for the imposition of sentence upon Par.

No Other Promises

This agreement and the Exhibits hereto constitute the plea agreement between Par and this Office and together their terms supersede any previous agreements between them. No additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties.

Very truly yours,

PAUL J. FISHMAN  
United States Attorney

By:   
JOSEPH MACK  
Assistant U.S. Attorney  
SHANNON SINGLETON  
Special Assistant U.S. Attorney

APPROVED:

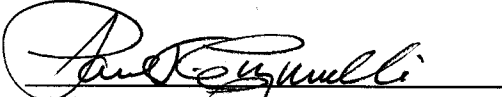


MAUREEN A. RUANE  
Chief, Health Care and Government Fraud Unit



I am the authorized corporate representative for Par Pharmaceutical Companies, Inc. ("Par"). I have received this letter from John N. Nassikas, Esq., who is the attorney for Par. I have read the letter, and Mr. Nassikas and I have discussed it and all of its provisions, including those addressing the charge, sentencing, stipulations, forfeiture and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this agreement. I understand this letter fully. On behalf of and with the express authorization of Par, I hereby accept its terms and conditions and acknowledge that it constitutes the plea agreement between the parties. Par understands that no additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties. Par wants to plead guilty pursuant to this plea agreement.

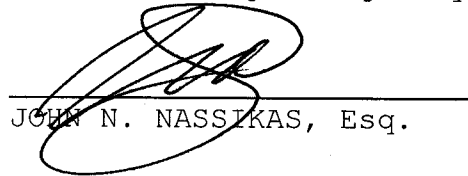
AGREED AND ACCEPTED:



Date: 3/4/13

PAUL V. CAMPANELLI  
As Authorized Corporate Representative  
for Par Pharmaceutical Companies, Inc.

I am counsel for Par Pharmaceutical Companies, Inc. ("Par"). I have discussed with my client this plea agreement and all of its provisions, including those addressing the charge, sentencing, stipulations, forfeiture and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this agreement. Further, I have fully advised the authorized corporate representative, Paul V. Campanelli, of Par's rights regarding this plea agreement and all of its provisions, including those addressing the charge, sentencing, stipulations, and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this agreement. My client, Par, understands this plea agreement fully and wants to plead guilty pursuant to it.



JOHN N. NASSIKAS, Esq.

Date: 3/4/13

Schedule A

1. This Office and Par agree to stipulate to the following facts:

Beginning in or about July 2005 and continuing until in or about 2009, in the District of New Jersey and elsewhere, Par Pharmaceutical Companies, Inc., through its branded drug division that was first called the Proprietary Products Division and that was thereafter re-named Strativa Pharmaceuticals, did introduce and deliver for introduction, and cause the introduction or delivery for introduction, into interstate commerce, quantities of Megace® ES for an unapproved use, namely the treatment of geriatric wasting, and that Megace® ES was misbranded in that the labeling for Megace® ES lacked adequate directions for such use.

2. In accordance with the above, and pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the parties agree that the following sentence (hereinafter the "Stipulated Sentence") is reasonable taking into account all of the factors under 18 U.S.C. §§ 3553(a) and 3572:

(a) Par shall pay a criminal fine in the amount of \$18,000,000 within seven (7) days after sentencing;

(b) Par shall pay a special assessment of \$125;

(c) Par shall pay forfeiture in the amount of \$4,500,000, and such amount shall be paid prior to the time of the plea hearing;

(d) Par shall not be ordered to pay restitution; and

(e) Par shall not be subject to a term of probation.

3. The parties further agree that neither party will argue for a sentence that varies from any of the terms of the Stipulated Sentence.



EXHIBIT 1

PAR'S ENHANCED COMPLIANCE MEASURES AND CERTIFICATION OBLIGATIONS

Par Pharmaceutical Companies, Inc., through its subsidiary Par Pharmaceutical, Inc. (collectively "Par") reports that it has instituted and will maintain policies and procedures, including a Compliance Program<sup>1</sup> to prevent future violations of the Federal Food, Drug, and Cosmetic Act in its sales, marketing and promotion of its pharmaceutical products, including but not limited to Megace® ES, and for five (5) years following entry of a plea in this matter, Par agrees to do the following:

A. Notification of Settlement

Within ten (10) days of entering its plea of guilty, Par will prominently feature on its website the plea agreement and all attached Exhibits, the criminal Information, and the Corporate Integrity Agreement.

Within thirty (30) days of entering its plea of guilty, Par will send a letter to all health care providers that it currently "details" or with whom it has had any business contact within the six (6) months prior to the date of entering its plea of guilty. Par's letter will describe the complete terms of the criminal plea, including the terms included in this Exhibit 1, Par's Enhanced Compliance Measures and Certification Obligations, and will also contain a link to the page on Par's website described above.

B. Megace® ES "Acknowledgment Letter"

Effective as of the date of its plea, Par shall immediately modify the language in the "Acknowledgment Letter" used by its sales representatives (currently stored and shown in an electronic format) to "detail" or "call upon" health care practitioners regarding Megace® ES as follows:

(1) The Acknowledgment Letter shall accurately state the FDA-approved indication for Megace® ES, and shall thereafter state that the FDA-approved indication is the only use

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<sup>1</sup> "Compliance Program" refers to the policies, procedures, practices, and other measures that Par has established or will establish to address regulatory compliance issues relating to the marketing, promotion and sale of pharmaceutical products.

that any sales representative may discuss with the health care practitioner; and

(2) The Acknowledgment Letter shall state that if the health care practitioner has any questions about Megace® ES outside of or beyond the FDA-approved indication, all such inquiries shall be directed to Par's Medical Affairs personnel.

C. Compensation and Incentives Not Based on Sales

Par will maintain policies and procedures that shall (1) be designed to ensure that financial incentives do not inappropriately motivate sales representatives or their managers to engage in improper promotion, sales, and marketing of Par's pharmaceutical products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation any sales that may indicate off-label promotion of Par's pharmaceutical products.

Pursuant to this agreement, effective April 1, 2013, Par shall not provide any financial reward (through compensation, including incentive compensation or otherwise) or discipline (through employment action of any kind) to its branded product sales representatives or their managers based upon the volume of sales of Megace® ES within any given employee's territory or the area of any given manager's supervision.

D. Certifications and Reporting to the United States

Par shall provide an annual Chief Executive Officer ("CEO") Certification<sup>2</sup> to the United States Department of Justice for five (5) years commencing after the date of sentencing, as described below. Each certification shall be sent to:

United States Attorney for the District of New Jersey  
United States Attorney's Office, District of New Jersey  
970 Broad Street, 7<sup>th</sup> Floor  
Newark, NJ 07102

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<sup>2</sup> "Certification" shall mean a statement sworn to under the penalty of perjury and that shall set forth that the representations contained therein may be provided to, relied upon, and are material to the United States, and that a knowingly false statement in the certification may result in criminal or civil liability for the signatory.

Before completing such certification each year, Par's CEO shall conduct a review of the effectiveness of Par's Compliance Program. The first review period shall run from the date of sentencing through a date 90 days after the date of sentencing. Thereafter, each review shall be conducted on an annual basis. The first certification is due 120 days after the date of sentencing, and each successive certification shall be due on the anniversary of the filing of the first certification.

Based on his or her review, Par's CEO shall submit to the United States a signed certification stating that, to the best of his or her knowledge, during the relevant time period:

(1) Par's Compliance Program continued to include the compliance policies and procedures set forth in the plea agreement dated January 3, 2013; and

(2) Par has not, in the last year, unlawfully marketed any of its pharmaceutical products, including but not limited to Megace® ES.

In addition to the above statement, the annual CEO Certification shall summarize the CEO's review, described above, that he or she has conducted in order to provide the required certification. In the event the CEO is unable to provide any part of this certification regarding Par's compliance, he or she shall provide a written explanation of why he or she is unable to provide such certification.

E. Breach of "Par's Enhanced Compliance Measures and Certification Obligations"

Par recognizes that each of the terms herein constitutes a material term. As a contractual remedy, Par and the United States agree that Par's failure to comply with any of the obligations set forth herein may lead to the imposition of the following monetary penalties (hereafter referred to as "Stipulated Penalties") in accord with the following provisions.

1. A Stipulated Penalty of \$20,000 per day for each day Par (a) fails to maintain any of the compliance measures set forth above (if more than one compliance measure fails to be maintained, the Stipulated Penalty will apply separately to each such compliance measure); or (2) fails to timely supply the annual CEO Certification. The Stipulated Penalty will begin to accrue on the day after the obligation was due.

2. Par may submit a timely written request for an extension of time to provide the annual Chief Executive Officer Certification. A written request is timely if received by the United States Attorney for the District of New Jersey at least five business days prior to the date by which the certification is due. Timely requests for extension will not be unreasonably denied. If an extension of time is granted in writing, Stipulated Penalties shall not accrue until one day after Par fails to meet the revised deadline. If not granted, Stipulated Penalties shall not begin to accrue until three business days after Par receives the United States' written denial of such request or the original due date, whichever is later.
3. Upon the sole determination of the United States Attorney for the District of New Jersey that Par has failed to comply with any of the obligations described herein, the United States shall notify Par in writing of Par's failure to comply and of the United States' exercise of its contractual right to demand payment of the Stipulated Penalties (the "Demand Letter"). The Demand Letter shall set forth: (i) the provision breached; (ii) the date of the breach; (iii) a description of the breach sufficient to permit Par to cure if the breach is of a type that may be cured (as described below); and (iv) the amount of Stipulated Penalties claimed by the United States as of the date of the Demand Letter. Within fourteen (14) days after receipt of the Demand Letter, or such other period as to which the United States may agree in writing, Par shall attempt to cure the breach to the United States' reasonable satisfaction ("Cure Period"). If the breach is of a type that can be cured and Par cures the breach within the Cure Period, no Stipulated Penalties will be due. If Par fails to cure the breach during the Cure Period, but Par then subsequently cures the breach, Stipulated Penalties calculated from the date of breach to the date of cure shall be immediately payable to the United States. If the breach is one that cannot be cured, then stipulated penalties will be calculated from the date of the breach until the date that Par remediates the breach. The



Stipulated Penalties shall be paid by electronic fund transfer according to wire instructions that will be provided by the United States. A determination by the United States Attorney for the District of New Jersey regarding Par's failure to comply with any of the obligations described herein will be final and non-appealable. Par agrees that the United States District Court for the District of New Jersey shall have jurisdiction over any action to collect such a penalty.



**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
PAR PHARMACEUTICAL COMPANIES, INC.  
AND PAR PHARMACEUTICAL, INC.**

**I. PREAMBLE**

Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively, "Par") hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements).

Contemporaneously with this CIA, Par is entering into a Settlement Agreement with the United States. Par will also enter into settlement agreements with various states ("State Settlement Agreement") and Par's agreement to this CIA is a condition precedent to those agreements.

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by Par under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which Par is obligated to pay the Settlement Amount as set forth in the Settlement Agreement between Par and the United States. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 90 days after OIG's receipt of: (1) Par's final Annual Report; or (2) any additional materials submitted by Par pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

- a. all owners of Par who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading) and all directors of Par;
- b. all officers and employees of Par who are engaged in or supervise personnel who are engaged in any Covered Functions; and
- c. all contractors, subcontractors, agents, and other persons (including, but not limited to, third party vendors who provide services relating to the Covered Functions (as defined below in Section II.C.7)) who perform any Covered Function on behalf of Par and who in that capacity either: (1) interact directly with health care professionals ("HCPs"), health care institutions ("HCIs"), or consumers; or (2) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a Covered Person prior to execution or dissemination.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Government Reimbursed Products" refers to all Par products that are marketed or sold by Par in the United States or pursuant to contracts with the United States and that are reimbursed by Federal health care programs.

3. "Relevant Government Reimbursed Products" refers to all Par products that are marketed or sold by Par in the United States or pursuant to contracts with the United States and that are reimbursed by Federal health care programs, except

for Par's generic products that are marketed and sold to non-prescribing providers, such as wholesalers and pharmacies.

4. The term "Promotional Functions" includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to any applicable review committees.

5. The term "Product Related Functions" includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to HCPs and HCIs about Government Reimbursed Products, including those functions relating to Par's copy approval process or other applicable review committee(s) and activities by Par medical affairs ("Medical Affairs"); (b) contracting with HCPs and HCIs licensed in the United States to conduct post-marketing clinical trials, investigator sponsored studies (ISSs), and all other types of post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to post-marketing clinical trials and other post-marketing studies for Government Reimbursed Products (including studies of investigational and other uses and indications outside the currently approved uses and conditions of use); and (d) activities related to the submission of information about Government Reimbursed Products to compendia (such as DrugDex or other compendia of information about Government Reimbursed Products as defined below in Section III.B.2.r).

6. The term "Payer Related Functions" refers to Promotional Functions and Product Related Functions as they relate to interactions between Par and government payers, including the Federal government, state Medicaid programs, pharmacy benefits managers (PBM), or other individuals or entities under contract with or acting on behalf of Medicaid, Medicare Part D, and other government Payers (collectively "Payers").

7. The term "Covered Functions" refers to "Promotional Functions," "Product Related Functions," and "Payer Related Functions" collectively.

8. The term "Third Party Educational Activity" shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by Par, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

9. The term "Health Care Professionals" (HCPs) includes physicians, nurse practitioners, physician assistants, nurses, pharmacists, and dieticians.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Par shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Officer and Committee**

1. *Compliance Officer.* Within 90 days after the Effective Date, Par shall appoint a Covered Person to serve as its new Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements. The Compliance Officer shall be a member of senior management of Par, shall report directly to the Chief Executive Officer of Par, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Par Pharmaceutical Companies, Inc., and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Par as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Par shall report to OIG, in writing, any change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Par shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as legal, medical affairs, regulatory affairs, sales, marketing, human resources, research and development, audit, and operations). The Compliance Officer

shall chair the Compliance Committee, and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Par's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

Par shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board of Directors of Par Pharmaceutical Companies, Inc. (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Par's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee; and
- b. for each Reporting Period of the CIA, the Board shall adopt a resolution, signed by each member of the Board summarizing its review and oversight of Par's compliance with Federal health care program requirements, FDA requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors has made a reasonable inquiry into the operations of Par's Compliance Program for the time period [insert time period], including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Par has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to



provide the conclusion and the steps it is taking to implement an effective Compliance Program at Par.

Par shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Accountability and Certifications*: In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Par officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer; President; Executive Vice President and Chief Financial Officer; Senior Vice President, Brand Sales and Marketing; Senior Vice President, Corporate Regulatory Affairs; Senior Vice President, Corporate Quality and Compliance; Senior Vice President, Sales; Director, Medical Affairs; and, to the extent that a business unit performs Covered Functions and is not covered by the certification of one of the above-listed individuals, such other executives, vice-presidents, and directors of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the \_\_\_\_\_ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Par policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the \_\_\_\_\_ [insert name of department or functional area] of Par is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons

why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards

1. *Code of Conduct.* Within 120 days after the Effective Date, Par shall update and distribute its written Code of Conduct to all employees and other Covered Persons. Par shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Par's commitment to full compliance with all Federal health care program requirements and FDA requirements, including its commitment to comply with all requirements relating to the Covered Functions;
- b. Par's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements, FDA requirements, and with Par's own Policies and Procedures;
- c. the requirement that all of Par's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Par, suspected violations of any Federal health care program requirements, FDA requirements, or of Par's own Policies and Procedures;
- d. the personal obligation of each Covered Person to comply with Federal health care program requirements, FDA requirements, and Par's Policies and Procedures; and
- e. the right of all individuals to use the Disclosure Program described in Section III.F, and Par's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Par's Code of Conduct. New Covered Persons shall receive the Code of

Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Par shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* Within 120 days after the Effective Date, Par shall implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Par's compliance with Federal health care program requirements and FDA requirements. At a minimum, the Policies and Procedures must address the following:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;
- c. appropriate ways to conduct Product Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;
- d. the materials and information that may be distributed by Par sales personnel about Government Reimbursed Products and the manner in which Par sales personnel respond to requests for information about non-FDA approved (or "off-label") uses of Government Reimbursed Products. These Policies and Procedures shall require that sales personnel may not

engage in off-label promotion (directly or indirectly) and must refer all requests for information about off-label uses of Government Reimbursed Products to Medical Affairs;

- e. the materials and information (including product information and product dossiers about Government Reimbursed Products) that may be distributed by Medical Affairs and the mechanisms through, and manner in which, Medical Affairs receives and responds to requests for information from an HCP or another individual or entity about off-label uses of Par's Government Reimbursed Products; the form and content of information disseminated by Par in response to such requests; and the internal review and approval process for the information disseminated.

The Policies and Procedures shall include a requirement that Medical Affairs use a database ("Inquiries Database") to track all requests for information about Government Reimbursed Products to Medical Affairs. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Par's products: (1) date of Inquiry; (2) form of Inquiry (e.g., fax, phone, etc.); (3) name of the requesting HCP, HCI, or other individual or entity; (4) nature and topic of request (including exact language of the Inquiry if made in writing); (5) an evaluation of whether the Inquiry relates to information about an off-label use for the product (on-label, off-label, or unable to determine); (6) nature/form of the response from Par (including a record of the materials provided to the HCP or HCI in response to the request); and (7) the name of the Par representative who called on or interacted with the HCP, customer, or HCI, if known;

- f. the materials and information that may be distributed or made available by Par through social media and/or through direct-to-consumer advertising. These Policies and Procedures shall be designed to ensure that Par's activities in this area and the information distributed or made available complies with all applicable Federal health care program and FDA

requirements, and have been reviewed and approved by Par's review committee before they are disseminated;

- g. the manner and circumstances under which medical personnel from Medical Affairs interact with or participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to unsolicited requests about off-label indications of Government Reimbursed Products;
- h. the development, implementation, and review of call plans for sales personnel and other Par personnel who promote and sell Relevant Government Reimbursed Products (Call Plans). For each Relevant Government Reimbursed Products, Par shall develop a Call Plan. The Policies and Procedures shall require that Par review Call Plans for the product and the bases upon, and circumstances under which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the Call Plans. The Policies and Procedures shall also require that Par modify the Call Plans as necessary to ensure that Par is promoting Relevant Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The Call Plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Relevant Government Reimbursed Product;
- i. the development, implementation, and review of policies and procedures for the distribution of samples of, or coupons or vouchers for, Government Reimbursed Products (collectively Sample Distribution Policies and Procedures). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples, coupons, or vouchers from Par. Par shall modify the Sample Distribution Policies and Procedures as necessary to ensure that Par is promoting Government Reimbursed Products in a

manner that complies with all applicable Federal health care program and FDA requirements;

- j. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and shall include requirements about the content and circumstances of such arrangements and events;
- k. programs to educate sales personnel promoting a Government Reimbursed Product, including but not limited to presentations by HCPs at sales meetings and experience-based learning activities, if any. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;
- l. sponsorship or funding of grants to healthcare-related organizations and charitable contributions. These Policies and Procedures shall be designed to ensure that Par's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- m. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.8 above. These Policies and Procedures shall be designed to ensure that any Par funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA

requirements. During the term of the CIA, the Policies and Procedures shall continue to require that if Par provides funding for Third Party Educational Activity, such funding must be in accordance with its Policies and Procedures and practices outlined in this Section III.B.2.m and below in Section III.M.4.

The Policies and Procedures shall also require that: (1) Par disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with this subsection III.B.2.m, any financial relationships with faculty, speakers, or organizers at such Activity; (2) as a condition of funding, the third party shall agree to disclose Par's financial support of the Third Party Educational Activity and to require faculty, speakers, or organizers at such Activity to disclose any financial relationship with Par; (3) the Third Party Educational Activity have an educational focus; (4) the content, organization, and operation of the Third Party Educational Activity (including the faculty, educational methods, materials, and venue) be independent of Par's control; (5) Par support only Third Party Educational Activity that is non-promotional in tone/nature; and (6) Par's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational Activity that is fair, balanced, accurate and not misleading;

- n. review of promotional materials and information intended to be disseminated outside Par by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Par's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require that: (1) Par's Copy Review Committee review all promotional materials prior to the distribution or use of such



materials; (2) Par's copy review and approval process ensure that FDA communications relevant to the product are considered and appropriately reflected in promotional materials and in a copy approval repository maintained by each review committee; and that (3) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

- o. sponsorship, funding of, and disclosures relating to Product Related Functions. These Policies and Procedures shall be designed to ensure that Par's funding, sponsorship, and disclosure complies with all applicable Federal health care program and FDA requirements;
- p. compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives promoting a Government Reimbursed Product and that sales representative's direct supervisor. These Policies and Procedures shall: (1) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Par's Government Reimbursed Products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate off-label promotion of Government Reimbursed Products.

Effective April 1, 2013, Par shall not provide any financial reward (through compensation, including incentive compensation or otherwise) or discipline (through employment action of any kind) to its sales representatives or their direct managers based upon the volume of sales of non-generic megestrol acetate product within any given employee's territory or the area of any given manager's supervision. The sales force incentive compensation program is described in more detail below in section III.H. Par shall continue this sales force incentive compensation program, or a substantially equivalent program, during the term of the CIA;

- q. Par's right to recoup or cause the forfeiture of annual performance pay of Par employees and Covered Executives, as defined in Appendix D, if certain triggering events relating to misconduct by the employees or executives occur described in more detail below in section III.H;
- r. the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (e.g., any changes based on Par's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia.) The Policies and Procedures shall include a requirement that when Par makes any submission of information to any Compendia, Par shall conduct an annual review of (i) all information in the compendia about Government Reimbursed Products designed to ensure the information is complete and accurate and (ii) all arrangements, processing fees, or other payments or financial support (if any) provided by Par to any Compendia. Par compliance personnel shall be involved in this review;
- s. sponsorship by Par of human subject research of Government Reimbursed Products, including the decision to provide financial or other support for research and decisions regarding the manner in which the research support is provided. The Policies and Procedures for Relevant Government Reimbursed Products must address post-marketing clinical trials and post-marketing studies and support by Par of investigator-sponsored studies of Relevant Government Reimbursed Products (collectively, "Research"), including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research, including

the support for publication of information about the Research results and outcomes; uses made of publications relating to Research;

- t. authorship of journal articles and other publications about Research or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and Par; the identification of all authors or contributors (including professional writers); and the scope and breadth of research results be made available to each author or contributor;
- u. conducting Payer Related Functions in compliance with all applicable Federal healthcare program requirements, FDA requirements, and other requirements; and
- v. disciplinary policies and procedures for violations of Par's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

Within 120 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Par shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education

1. *General Training.* Within 120 days after the Effective Date, Par shall provide at least one hour of General Training to each U.S. based Covered Person, except those engaged in manufacturing and facilities functions. This training, at a minimum, shall explain Par's:

- a. CIA requirements; and

b. Compliance Program, including the Code of Conduct.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Par shall provide annual training to each U.S. based Covered Person, except those engaged in manufacturing and facilities functions. The Specific Training shall relate to his or her specific job responsibilities. This training shall be known as Specific Training.

Within 120 days after the Effective Date, these Covered Persons shall receive at least three hours of Specific Training in addition to the General Training required above.

This Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Covered Functions;
- b. all applicable FDA requirements relating to Covered Functions;
- c. all Par Policies and Procedures and other requirements applicable to Covered Functions;
- d. the personal obligation of each individual involved in Covered Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- f. examples of proper and improper practices related to Covered Functions.

New Covered Persons shall receive their Specific Training within 30 days after the beginning of their employment or within 120 days of the Effective Date, whichever is later. A Par employee who has completed the Specific Training shall oversee a new Covered Person's work, to the extent that the work relates to any of the Covered Functions, until such time as the new Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

3. *Compliance Training for Management.* Within 120 days of the Effective Date, Par shall provide to managers of employees performing Covered Functions and supervisors of sales personnel (collectively "Management") at least two hours of specialized compliance-related training applicable to the functional area of the manager (Management Compliance Training). This training shall address the responsibility of Management to promote compliance and to identify and mitigate compliance-related risks in their functional areas.

New members of Management shall receive the Management Compliance Training within 30 days after becoming a member of Management or within 120 days of the Effective Date, whichever is later.

After receiving the initial Management Compliance Training described in this Section, each member of Management shall receive at least two hours of Management Compliance Training in each subsequent Reporting Period.

4. *Board Member Training.* Within 120 days after the Effective Date, Par shall provide at least two hours of training to each member of the Board of Directors of Par Pharmaceutical Companies, Inc., in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a board member or within 120 days after the Effective Date, whichever is later.

5. *Certification.* Each Covered Person who is required to complete training shall certify, in writing or in electronic form, if applicable, that he or she has received such training. The certification shall specify the type of training received and

the date received. The Compliance Officer (or designee) shall retain these certifications, along with all course materials. These shall be made available to OIG, upon request.

6. *Qualifications of Trainer.* Persons responsible for providing the training described above shall be knowledgeable about the subject area of the training, including about applicable Federal health care program and FDA requirements.

7. *Update of Training.* Par shall review its training annually, and, where appropriate, shall update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during internal audits or the IRO Reviews, the risk assessment and mitigation processes program (defined below in Section III.D), and any other relevant information.

8. *Computer-based Training.* Par may provide the training required under this CIA through appropriate computer-based training approaches. If Par chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

#### D. Risk Assessment and Mitigation Processes.

Prior to Effective Date of the CIA, Par implemented Enterprise Risk Management (ERM) processes. Par represents it designed the ERM process to generate a strategic risk assessment for each of Par's functional operating areas and business units. Within 120 days after the Effective Date, Par shall modify the ERM process as necessary to meet the requirements of the CIA and Appendix C by developing a standardized, centralized process to allow Par legal, compliance, and other personnel to identify and assess risks associated with the marketing and promotion of Government Reimbursed Products, and to devise and implement specific measures to mitigate the identified risks. This process shall focus on the risks associated with Government Reimbursed Products, including the areas of: safety, marketing, sales, promotion issues (including the risk of off-label promotion), and healthcare compliance risks. Based on the outcomes of the risk identification and assessment process, Par legal, compliance and other personnel shall centrally develop and implement specific plans designed to mitigate or reduce the identified risks. The IRO review of the ERM process is described in more detail in Appendix C. Par shall maintain the ERM process for the duration of the CIA.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Par shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Par in assessing and evaluating its Covered Functions. More specifically, the IRO(s) shall conduct reviews that assess Par's systems, processes, policies, procedures, and practices relating to the Covered Functions and the ERM process (collectively "IRO Reviews").

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Par shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the IRO Review including expertise in the pharmaceutical industry with regard to risk identification and mitigation in relation to pharmaceutical product marketing and promotion. Each IRO shall assess, along with Par, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

- b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendices B and C, the IRO Reviews shall consist of three components: (1) Systems Reviews and Transactions Reviews relating to the Covered Functions; (2) Additional Items reviews; and (3) Systems Reviews and Transaction Reviews relating to the ERM program. The Systems Reviews shall assess Par's systems, processes, policies, and procedures relating to the Covered Functions and the ERM program. If there are no material changes in Par's relevant systems, processes, policies, and procedures, the Systems Review shall be performed for the



periods covering the first and fourth Reporting Periods. If Par materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform Systems Reviews for the Reporting Period in which such changes were made in addition to conducting a Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendices B and C.

The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendices B and C, the Transactions Review shall include several components.

In addition, the Transactions Review shall also include a review of up to four additional areas or practices of Par identified by the OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular IRO Reporting Period, the OIG will consult with Par and may consider internal audit work conducted by Par, the Government Reimbursed Product portfolio of Par, the nature and scope of Par's promotional practices and arrangements with HCPs and HCIs, any additional types of non-promotional activities engaged in by Par, including but not limited to advisory boards, post-marketing research, physician publications, and other information known to it.

As set forth more fully in Appendix B, Par may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow Par's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify Par of the nature and scope of the IRO review for each of the Additional Items not later than 150 days prior to the end of each applicable IRO Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or

Par shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

- c. *Retention of Records.* The IRO and Par shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Par) related to the IRO Reviews.

2. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in each IRO Review Report is described in Appendices B and C.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any of Par's IRO Reviews fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Par shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Par's final Annual Report shall be initiated no later than one year after Par's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Par of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Par may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. Par agrees to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with Par prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Par a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section

III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A.

F. Disclosure Program

Prior to the Effective Date, Par established a Disclosure Program that includes a mechanism (e.g., a toll-free Compliance Hotline) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Par's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Par publicizes the existence of the Compliance Hotline (e.g., via periodic e-mails to employees, posting the information in prominent common areas, or through references in the Code of Conduct and during training).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Par shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. This disclosure log shall be made available to OIG upon request.

G. Ineligible Persons

1. *Definitions.* For purposes of this CIA:

- a. an "Ineligible Person" shall include an individual or entity who:

- i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. "Exclusion Lists" include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

2. *Screening Requirements.* Par shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Par shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Par shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.
- c. Par shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in Section III.G affects Par's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Par understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Par may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Par meets the requirements of Section III.G.

3. *Removal Requirement.* If Par has actual notice that a Covered Person has become an Ineligible Person, Par shall remove such Covered Person from responsibility for, or involvement with, Par's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Par has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term Par shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

#### H. Employee and Executive Incentive Compensation Restriction Program and Executive Financial Recoupment Program.

Par agrees that Par will maintain policies and procedures that shall (1) be designed to ensure that financial incentives do not inappropriately motivate sales representatives or their direct managers to engage in improper promotion, sales, and marketing of Par's pharmaceutical products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation any sales that may indicate off-label promotion of Par's pharmaceutical products.

Effective April 1, 2013, Par agrees that it will not provide financial reward (through compensation, including incentive compensation or otherwise) or discipline (through tangible employment action) its prescribing-customer-facing field sales professionals (pharmaceutical sales representatives) or their direct managers based upon

the volume of sales of any non-generic megestrol acetate product within a given employee's own territory or the manager's district (Employee and Executive Incentive Compensation Restriction Program). Par shall maintain its Employee and Executive Incentive Compensation Restriction Program, or a substantially equivalent program, during the term of this CIA. Par commits to maintaining for at least the duration of the CIA, absent agreement otherwise with the OIG, these restrictions on incentive compensation.

In addition, Par agrees that by 2014, except as may be required in connection with local controlling law, Par shall establish and maintain throughout the term of the CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay for an executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). This financial recoupment program shall apply to Covered Executives (as defined in Appendix D) who are either current Par employees or who are former Par employees at the time of a Recoupment Determination. The specific terms and conditions of the Executive Financial Recoupment Program are set forth in Appendix D. Par commits to maintaining an Executive Financial Recoupment Program consistent with the terms of Appendix D for at least the duration of the CIA absent agreement otherwise by the OIG.

I. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, Par shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Par conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that Par has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Par shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

J. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any

Federal health care program for which penalties or exclusion may be authorized;

b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any FDA requirements relating to the promotion of Government Reimbursed Products (including an FDA Warning Letter issued to Par);

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by Par.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Par determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Par shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.J.1.a-c.* For Reportable Events under Sections III.J.1.a-c, the report to OIG shall include:

a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program or FDA authorities implicated;

b. a description of Par's actions taken to correct the Reportable Event; and

c. any further that steps Par plans to take to address the Reportable Event and prevent it from recurring.

Par shall not be required to report any Reportable Event which is the subject of an ongoing investigation or legal proceeding by a governmental entity or its agents previously disclosed under Section III.I above.



4. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA authorities implicated.

K. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between Par and the FDA that materially discusses Par's or a Covered Person's actual or potential unlawful or improper promotion of Par's products (including any improper dissemination of information about off-label indications), Par shall provide a copy of the report, correspondence, or communication to the OIG. Par shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

L. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, or as excepted in Section III.L.1, within 120 days after the Effective Date, Par shall establish a comprehensive Field Force Monitoring Program with respect to Government Reimbursed Products (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) a Speaker Monitoring Program if Par engages in speaker program activities; (2) direct field observations (Observations) of sales personnel; and (3) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.* Par represents that it currently does not engage in speaker program activities. If Par begins activities in this area, within 90 days after beginning the activity, Par shall notify OIG that it is engaged in the new type of activity and develop and implement a monitoring program for speaker program activity.

The Potential IRO Review of these activities is described in Appendix B. This program shall be referred to as the Speaker Monitoring Program.

If Par engages in speaker program activities,

- a. Par shall maintain processes to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use Par approved materials and may not directly or indirectly promote the product for off-label uses.)
- b. Par shall maintain a centralized electronic system through which all speaker programs are administered. This system shall establish controls regarding eligibility and qualifications of speakers and venues for the programs and require that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by Par.
- c. Par shall maintain a comprehensive list of speaker program attendees through its centralized system.
- d. Par shall track and review the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs conducted during each Reporting Period.
- e. Par shall require certified evaluations by sales personnel regarding whether a speaker program complied with Par requirements, and in the event of non-compliance, Par shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.
- f. Par shall institute a Speaker Monitoring Program under which Par compliance or other appropriately trained Par personnel who are independent from the functional area being monitored (hereinafter "Par Monitoring Personnel") shall attend speaker programs during each Reporting Period and conduct live audits at least 10 percent of such programs ("Speaker Program Audits"). If Par does not conduct any speaker programs during a Reporting Period, Par Monitoring Personnel are not required to conduct audits of speaker programs during that Reporting Period. If Par conducts 10 or fewer speaker programs in a Reporting Period, Par shall consult with OIG to determine the number of Speaker Program Audits in that Reporting Period.

The programs subject to Speaker Program Audits shall be selected both on a risk-based targeting approach and on a sampling approach. For each program reviewed, personnel conducting the Speaker Program Audits shall review slide materials and other materials used as part of the speaker program, speaker statements made during the

program, and Par representative activities during the program to assess whether the programs were conducted in a manner consistent with Par's Policies and Procedures. Par shall maintain the controls around speaker programs as described above, and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, Par Monitoring Personnel shall conduct observations of field personnel (e.g., sales personnel and account managers) to assess whether the messages delivered and materials distributed to HCPs, HCIs, and others are consistent with applicable legal requirements and with Par's Policies and Procedures. These observations shall be full day ride-alongs with the field personnel (Observations), and each Observation shall consist of directly observing all meetings between field personnel and HCPs during the workday. The Observations shall be scheduled throughout the year, selected by Par Monitoring Personnel both on a risk-based targeting approach and on a sampling approach, include multiple therapeutic areas treated by Government Reimbursed Products and actively promoted products, and be conducted across the United States. At the completion of each Observation, Par Monitoring Personnel shall prepare a report which includes:

- 1) the identity of the field personnel;
- 2) the identity of the Par Monitoring Personnel;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Par policy; and
- 6) the identification of any potential off-label promotional activity or other improper conduct by the field personnel.

Par Monitoring Personnel shall conduct at least 20 Observations during each Reporting Period.

3. *Records Reviews.* As a component of the FFMP, Par shall also review various types of records to assess sales personnel interactions with HCPs and HCIs with respect to Relevant Government Reimbursed Products in order to identify potential or actual compliance violations. For each Reporting Period, Par shall develop and implement a plan for conducting Records Reviews associated with up to three Relevant Government Reimbursed Products and a sampling of the personnel supporting those products in regions across the country (as agreed with the OIG for each Reporting Period.) The OIG shall have the discretion to identify up to three Relevant Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the products based on information about Par's products provided by Par, upon request by the

OIG no later than 60 days prior to the beginning of the Reporting Period, and other information known to the OIG. If the OIG does not identify the Relevant Government Reimbursed Products to be reviewed within the first 30 days of the Reporting Period, Par shall select one product to be reviewed.

These Records Reviews shall include the monitoring and review of: (1) records and systems relating to sales personnel interactions with HCPs and HCIs (including records from any call reporting system used by sales personnel), including sales communications from managers, coaching reports, sample distribution records, and expense reports; (2) requests for medical information about, or inquiries relating to, Relevant Government Reimbursed Products; (3) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of sales personnel interactions with HCPs and HCIs; (4) sales personnel e-mails and other electronic records; and (5) recorded results of the Observations of sales representatives and applicable notes or information from the sales personnel managers.

4. *Reporting and Follow-up.* Personnel conducting the Speaker Program Audits, Observations, and Records Reviews shall have access to all relevant records and information necessary to assess potential or actual compliance violations. Results from the FFMP audits, including the identification of potential violations of policies and/or legal requirements, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate. In the event that a potential violation of Par's Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect of the FFMP, Par shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.J above, if applicable. Any compliance issues identified during a Speaker Program Audit, Observation and/or Records Review and any corrective action shall be recorded in the files of the Compliance Officer (or compliance personnel designee).

Par shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, Par also shall provide the OIG with copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Par took as a result of such determinations. Par shall make the Observation reports for all other Observations available to the OIG upon request.

M. Monitoring of Non-Promotional Activities.

Par represents that it currently does not use advisory boards, engage in publication activities, support post-marketing Research, or provide medical education grants. If Par begins activities in these areas with respect to Government Reimbursed Products, within 90 days after beginning the activity, Par shall notify OIG that it is engaged in the new type of activity. During all Reporting Periods in which Par engages in the new type of activity, Par shall also develop and implement a monitoring program for the activity. Within 60 days of notifying OIG that Par is engaged in the new type of activity, Par shall submit to the OIG a proposed monitoring plan (Monitoring Plan) that will cover the new type of activity.

Par's Monitoring Plan for each Reporting Period shall include a summary and an explanation of the type of activities to be monitored, the proposed monitoring method, the number of activities to be monitored, and, if applicable, a description of how the proposed plan modifies the Monitoring Plan for a particular activity in comparison to the Monitoring Plan for the prior Reporting Period. OIG shall have the right to review, propose changes to, or object to each proposed Monitoring Plan. In the event OIG does not notify Par of any objection to the applicable Monitoring Plan and/or propose modifications within 60 days, Par may proceed to implement the proposed Monitoring Plan. Par shall conduct monitoring of all new types of activity in accordance with the terms of the Monitoring Plan(s) approved by or submitted to the OIG.

The potential IRO Review of these activities under the Additional Items Review is described in Appendix B.

To the extent not already accomplished, within 120 days after the Effective Date Par shall develop and implement a monitoring program for consultant arrangement activities. In addition, if Par engages in Research-related activities, publications, or grants, Par shall develop and implement a monitoring program for that activity. The monitoring program for consultant arrangement activities and for any future Research-related activity, publication, or grant are collectively referred to as the Non-Promotional Monitoring Program.

1. *Consultant Arrangement Activities.* To the extent that Par engages U.S.-based HCPs or HCIs for services that relate to Promotional Functions or to Product Related Functions other than for speaker programs, Research-related activities, or publication activities (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as Consultants. Par shall require all Consultants

to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Par.

To the extent not already accomplished, within 120 days after the Effective Date, Par shall establish a process to develop annual budgeting plans that identify the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the following year. The annual Consultant budgeting plans shall also identify the budgeted amounts to be spent on Consultant-related activities. Par's Compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate purposes in accordance with applicable Par Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, Par shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the Consultant arrangement (e.g., information about the numbers and qualifications of the HCPs or HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and type of work product to be generated.) Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Par Compliance personnel.

To the extent not already accomplished, within 120 days after the Effective Date, Par shall amend its Policies and Procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, Par received the work product generated by the Consultant.

Within 120 days after the Effective Date, Par shall establish a Consultant Monitoring Program through which it shall conduct audits for each Reporting Period (Consultant Program Audits) of at least 10 percent of Consultant arrangements with HCPs related to Relevant Government Reimbursed Products for each Reporting Period. If Par does not engage any Consultants during a Reporting Period, Par Monitoring Personnel are not required to conduct audits of any Consultant arrangements during that Reporting Period. If Par engages 10 or fewer Consultants in a Reporting Period, Par shall



consult with OIG to determine the number of Consultant Program Audits for that Reporting Period.

The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach. Par Monitoring Personnel conducting the Consultant Program Audits shall review needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Par's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

2. *Research-Related Activities.* To the extent that Par engages or supports U.S.-based HCPs or HCIs to conduct post-marketing clinical trials or other types of Research relating to Relevant Government Reimbursed Products, such HCPs and HCIs shall be referred to collectively as "Researchers". Par shall require all Researchers to enter written agreements describing the scope of the clinical research or other Research to be performed, the fees to be paid or support to be given, and compliance obligations for the Researchers. Researchers retained to conduct Research shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Par.

If Par engages or supports Researchers, Par shall establish an annual budgeting plan for Researchers that identifies the business or scientific need or scientific opportunity for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year. The annual Researcher budgeting plan shall also identify the budgeted amounts to be spent on Researcher-related activities during the year. Par Compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Research arrangements and related events are used for legitimate purposes in accordance with Par Policies and Procedures.

If Par engages or supports Researchers, Par shall establish a process to ensure that a needs assessment has been completed to justify the retention of the Researcher prior to the retention of the Researcher. The needs assessment shall identify the business or scientific need for the information to be provided by the Researcher and provide specific details about the Research arrangement (including, for example, information about the



numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated). Any deviations from the Researcher budgeting plans shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Par Compliance personnel.

If Par engages or supports Researchers, within 90 days of beginning this program, Par shall amend its Policies and Procedures in a manner designed to ensure that each Researcher performed the work for which the Researcher was engaged.

3. *Publication Activities.* To the extent that Par engages U.S.-based HCPs or HCIs to produce articles or other publications relating to Relevant Government Reimbursed Products (collectively "Publication Activities") such HCPs or HCIs shall be referred to as Authors. Par shall require all Authors to enter written agreements describing the terms of the arrangement between Par and the Author and compliance obligations of the Authors. Authors shall be paid according to the centrally managed, pre-set rate structure that is established for Research related activities. If Par engages in Publication Activities, Par shall determine whether there is a business need for the publication(s) prior to retaining the author. If Par engages in Publication Activities, Par shall establish a plan for publications for the year, which shall include a budget for publications.

4. *Grant Activities.* Par represents that it does not provide medical education grants and otherwise provides limited grants. If Par provides medical education grants, Par shall provide medical education grants only to educational providers (including academic medical centers, hospital or delivery systems, or professional medical associations that represent HCPs who deliver patient care) that satisfy pre-set criteria established by Par. Par shall establish policies and procedures so that Par's commercial organization (including the sales and marketing departments) has no involvement in, or influence over, the review and approval of medical education grants. Medical education grants shall not be related to the promotion of a Government Reimbursed Product. Par shall continue the medical education grant process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date.

5. *Follow Up Reviews and Reporting.* In the event that a potential violation of Par's Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during any aspect of the Non-

Promotional Monitoring Program, Par shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.J above, if applicable. Any compliance issues identified during any Non-Promotional Monitoring Program referenced above, and any corrective action, shall be recorded in the files of the Compliance Department.

Par shall include a summary of the Non-Promotional Monitoring Program and the results of the Non-Promotional Monitoring Program as part of each Annual Report. As part of each Annual Report, Par also shall provide the OIG with descriptions of any instances identified through the Non-Promotional Monitoring Program in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Par's requirements or Policies and Procedures, and a description of the action(s) that Par took as a result of such determinations. Par shall make the documents relating to the Non-Promotional Monitoring Program available to the OIG upon request.

N. Notice to Health Care Providers and Entities. Within 90 days after the Effective Date, Par shall send, by first class mail, postage prepaid with delivery confirmation, a notice containing the language set forth below to all HCPs and HCIs that Par currently details. This notice shall be dated and shall be signed by the CEO of Par Pharmaceutical Companies, Inc. The body of the letter shall state the following:

As you may be aware, Par recently entered into a global civil, criminal, and administrative settlement with the United States and individual States in connection with the promotion and use of one of its products. This letter provides you with additional information about the settlement, explains Par's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that Par introduced misbranded quantities of Megace® ES into interstate commerce and that Par engaged in other improper conduct relating to Megace® ES. To resolve these matters, Par pled guilty to one misdemeanor criminal violation of the Federal Food, Drug, and Cosmetic Act and agreed to pay a criminal fine of \$18 million and to criminally forfeit an additional \$4.5 million. In addition, the Government alleged that Par violated the False Claims Act, and Par entered into a civil settlement to resolve these allegations pursuant to which Par

agreed to pay \$22.5 million to the Federal Government and State Medicaid programs. More information about this settlement may be found at the following: **[Par shall include a link to the USAO, DOJ Consumer Protection Branch, and Par websites in the letter.]**

As part of the federal settlement, Par also entered into a five-year corporate integrity agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. The CIA is available at <https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp>. Under this agreement, Par agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. Par also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by Par's representatives to Par's Compliance Department or the FDA.

Please call Par at XXXX or visit us at **[insert name of web link]** if you have questions about the settlement referenced above or to report any instances in which you believe that a Par representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by a Par representative to the FDA's Office of Prescription Drug Promotion at 301-796-9000. You should direct medical questions or concerns about the products to XXXXX.

The Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notices. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The log of all calls and messages received in response to the notices shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, Par shall provide to the OIG a summary of the calls and messages received.

O. Reporting of Physician Payments.

1. *Reporting of Payment Information.*

Quarterly Reporting: On or before August 30, 2013, Par shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities who or which received Payments (as defined in Section III.O.2, below) directly or indirectly from Par during the second quarter of 2013 and the aggregate value of such Payments. Thereafter, 60 days after the end of each calendar quarter, Par shall post on its website a report of the cumulative value of the Payments provided to each physician and Related Entity during the preceding calendar quarter.

Annual Reporting: On or before March 31, 2014, and 90 days after the end of each subsequent calendar year, Par shall post on its website a report of the cumulative value of the Payments provided to all U.S.-based physicians and Related Entities directly or indirectly from Par during the prior applicable calendar year. Each quarterly and annual report shall be easily accessible and readily searchable. The first annual report will contain information for the second through the fourth quarters of 2013.

Each listing made pursuant to this Section III.O shall include a complete list of all individual physicians or Related Entities to whom or which Par made Payments in the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or name of Related Entity. The Payment amounts in the lists shall be reported in the actual amount paid for all physicians or Related Entity on the listing. For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician has provided to Par for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

2. *Definitions and Miscellaneous Provisions.*

- (i) Par shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website during the term of the CIA. Par shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual and/or quarterly listings of

Payments. Nothing in this Section III.O affects the responsibility of Par to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entity.

- (ii) For purposes of Section III.O.1, "Payments" is defined to include all "payments or other transfers of value" as that term is defined in §1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder. The term Payments includes, by way of example, the types of payments or transfers of value enumerated in §1128G(a)(1)(A)(vi) of the Affordable Care Act. The term includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Par would otherwise report a Payment if made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by Par or by a vendor retained by Par to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.
- (iii) For purposes of its annual and quarterly website postings as described above, and only with regard to payments made pursuant to product research or development agreements and clinical investigations as set forth in § 1128G(c)(E) of the Affordable Care Act, Par may delay the inclusion of such payments on its website listings consistent with § 1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.
- (iv) The term "Payments" does not include transfers of value or other items that are not included in or are excluded from the definition of "payment" as set forth in § 1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder.
- (v) For purposes of this Section III.O, the term "Related Entity" is defined to be any entity by or in which any physician

receiving Payments is employed, has tenure, or has an ownership interest.

**P. Other Transparency/Disclosure Initiatives.**

Par shall require all Consultants to comply fully with all applicable disclosure obligations relating to their relationship with Par that may be externally imposed on the Consultants based on their affiliation with formulary or P&T committees or committees associated with the development of treatment protocols or standards. Par shall maintain this requirement throughout the term of this CIA. Within 120 days after the Effective Date, Par shall, if necessary, amend its policies relating to Consultants to explicitly state that Par requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Par that may be externally imposed on the Consultants based on their affiliation with formulary, P&T committees, or committees associated with the development of treatment protocols or standards or that are required by any HCL, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 150 days following the Effective Date, Par shall include an explicit requirement that the Consultants fully comply with all applicable disclosure requirements, as referenced above in this paragraph. Par shall continue these disclosure requirements throughout the term of this CIA.

To the extent not already accomplished, within 90 days after the Effective Date, Par shall post or make available information on its company website about FDA postmarketing commitments (PMCs). The Par website or links included therein shall provide access to general information about the PMC process, descriptions of ongoing Par studies, and information about the nature and status of the post-marketing commitments. Par shall continue to post or make available the above-described information about PMCs on its website or links included therein throughout the term of this CIA.

**IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Par changes locations or closes a business unit or location related to or engaged in any of the Covered Functions, Par shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.



B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Par purchases or establishes a new business unit or location related to or engaged in any of the Covered Functions, Par shall notify OIG no later than five days after the date that the purchase or establishment of the new business unit or location is publicly disclosed by Par. This notification shall include the address of the new business unit or location, phone number, fax number, the location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Par currently submits claims (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Par proposes to sell any or all of its business units or locations that are subject to this CIA, Par shall notify OIG of the proposed sale at no later than five days after the sale is publicly disclosed by Par. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

## V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Par shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the members of the Board of Directors referenced in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;

Par Corporate Integrity Agreement



5. a copy of Par's Code of Conduct required by Section III.B.1;
6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
7. a summary of all Policies and Procedures required by Section III.B.2 (a copy of such Policies and Procedures shall be made available to OIG upon request);
8. the following information regarding each type of training required by Section III.C:
  - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
  - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions..

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A; (d) a summary and description of any and all current and prior engagements and agreements between Par and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Par;
10. a description of the Disclosure Program required by Section III.F;
11. a description of the process by which Par fulfills the requirements of Section III.G regarding Ineligible Persons;
12. a certification by the Compliance Officer that the notice required by Section III.N was mailed to each HCP and HCI, the number of HCPs and HCIs to whom

or which the notice was mailed, a sample copy of the notice required by Section III.N, and a summary of the calls or messages received in response to the notice;

13. a certification from the Compliance Officer that, if required under Section III.O and to the best of his/her knowledge, information regarding Payments has been posted on Par's website as required by Section III.O;

14. a list of all of Par's locations engaged in Covered Functions (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of any each Federal health care program contractor to which Par currently submits claims (if applicable);

15. a description of Par's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

16. the certifications required by Section V.C.

B. Annual Reports. Par shall submit to OIG annually a report with respect to the status of, and findings regarding, Par's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors, or the group of Certifying Employees described in Sections III.A.2-4;

2. a copy of the resolution by the Board required by Section III.A.3;

3. the number of individuals required to review Par's Code of Conduct and complete the certifications required by Section III.B.1, the percentage of individuals who have completed such certifications, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

4. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in applicable requirements);

5. the following information regarding each type of training required by Section III.C:

a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete each type of training specified in Section III.C, percentage of individuals who completed the training, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. a summary of any significant changes to the Enterprise Risk Management program required by Section III.D;

7. a complete copy of all reports prepared pursuant to Section III.E, and Appendices B-C along with a copy of the IRO's engagement letters;

8. Par's response to the reports prepared pursuant to the reviews outlined in Section III.E and Appendices B-C, along with corrective action plan(s) related to any issues raised by the reports;

9. a summary and description of any and all current and prior engagements and agreements between Par and the IRO (if different from what was submitted as part of the Implementation Report);

10. certifications from the IRO regarding its professional independence and objectivity with respect to Par;

11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or Government Reimbursed Products;

Par Corporate Integrity Agreement

12. any changes to the process by which Par fulfills the requirements of Section III.G regarding Ineligible Persons;

13. a description of Par's employee and executive incentive compensation and recoupment programs required by Section III.H and Appendix D; a summary of any changes to such programs during the prior Reporting Period; and the information regarding Triggering Events and Recoupment Determinations required to be reported pursuant to Section E of Appendix D;

14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

15. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

16. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.K. This summary shall include a description of the matter and the status of the matter;

17. a summary of the FFMP and the results of the FFMP required by Section III.L, including copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Par took as a result of such determinations;

18. a summary of the Non-Promotional Monitoring Program and the results of the program described in Section III.M, including detailed description of any identified instances in which it was determined that the activities violated Par's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Par took as a result of such determinations;

19. a summary of the calls and messages received in response to the notice required by Section III.N and the disposition of those calls and messages;

20. a certification from the Compliance Officer that information regarding Payments has been posted on Par's website as required by Section III.O;

21. a description of all changes to the most recently provided list of Par's locations (including addresses) as required by Section V.A.14; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

22. a description of any additional, updated, supplemental or changed information submitted to any Compendia in accordance with Section III.B.2.r; and a description of all arrangements, processing fees, and other payments or financial support (if any) with or made to any Compendia evaluated during the annual review described in Section III.B.2.r; and

23. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. Certifying Employees: In each Annual Report, Par shall include the certifications of Certifying Employees as required by Section III.A.4;

2. Compliance Officer: In the Implementation Report, and each Annual Report, Par shall include the following individual certification by the Compliance Officer:

a. to the best of his or her knowledge, except as otherwise described in the report, Par is in compliance with the requirements of this CIA;

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;

c. Par's: (1) Policies and Procedures as referenced in Section III.B.2 above; (2) templates for standardized contracts and other similar documents; and (3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable

Federal health care program and FDA requirements. In addition, Par's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Par have been reviewed by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by Par and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request;

d. Par's Call Plans were reviewed at least once during the Reporting Period (consistent with Section III.B.2.h) and, for each product the Call Plans were found to be consistent with Par's policy objectives as referenced above in Section III.B.2.h; and

e. Par has maintained an employee and executive incentive compensation and recoupment program in accordance with the terms set forth above in Section III.H and Appendix D.

D. Designation of Information. Par shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Par shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

Par:

Thomas J. Haughey  
Par Pharmaceutical Companies, Inc.  
300 Tice Boulevard  
Woodcliff Lake, NJ 07677  
Telephone: 201.802.4000  
Facsimile: 201.802.4600

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Par may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

**VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Par's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Par's locations for the purpose of verifying and evaluating: (a) Par's compliance with the terms of this CIA; and (b) Par's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Par to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized



representative(s) may interview any of Par's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Par shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Par's employees may elect to be interviewed with or without a representative of Par present.

#### **VIII. DOCUMENT AND RECORD RETENTION**

Par shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

#### **IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Par prior to any release by OIG of information submitted by Par pursuant to its obligations under this CIA and identified upon submission by Par as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Par shall have the rights set forth at 45 C.F.R. § 5.65(d).

#### **X. BREACH AND DEFAULT PROVISIONS**

Par is expected to fully and timely comply with all of the CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Par and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Par fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;

- b. a Compliance Committee;
- c. the Board compliance obligations, including the resolution from the Board;
- d. the management accountability and certification obligations;
- e. a written Code of Conduct;
- f. written Policies and Procedures;
- g. the training of Covered Persons, Management, and Board Members;
- h. a modified Enterprise Risk Management program;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. an employee and executive incentive compensation and recoupment program as required by Section III.H and Appendix D;
- l. notification of Government investigations or legal proceedings as required by Section III.I;
- m. reporting of Reportable Events as required in Section III.J;
- n. notification of written communications with FDA as required by Section III.K;
- o. a program for FFMP as required by Section III.L;
- p. a program for Non-Promotional Monitoring Program as required by Section III.M;
- q. notifications to HCPs and HCIs as required by Section III.N;
- r. posting of any Payments as required by Section III.O; and

s. posting or making available other information required by Section III.P.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Par fails to engage and use an IRO as required in Section III.E and Appendices A-C.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Par fails to submit the Implementation Report or any Annual Report to OIG in accordance with the requirements of Section V of the CIA by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Par fails to submit any IRO Review report (including the IRO Initial Report) in accordance with the requirements of Sections III.E and Appendices A-C.

5. A Stipulated Penalty of \$1,500 for each day Par fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Par fails to grant access.)

7. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Par as part of its Implementation Report, the IRO Initial Report, or any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

8. A Stipulated Penalty of \$1,000 for each day Par fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Par stating the specific grounds for its determination that Par has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Par shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Par receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 7 of this Section.

B. Timely Written Requests for Extensions. Par may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this

Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Par fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Par receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Par has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Par of: (a) Par's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Par shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Par elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Par cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Par has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Par to report a Reportable Event and take corrective action as required in Section III.J of the CIA;
- c. a failure to engage and use an IRO in accordance with Section III.E and Appendices A-C;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; and
- e. a failure of the Board to issue a resolution in accordance with Section III.A.3 of the CIA.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Par constitutes an independent basis for Par's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Par has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Par of: (a) Par's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Par shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. Par is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30 day period, but that: (i) Par has begun to take action to cure the material breach; (ii) Par is pursuing such action with due diligence; and (iii)

Par has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Par fails to satisfy the requirements of Section X.D.3, OIG may exclude Par from participation in the Federal health care programs. OIG shall notify Par in writing of its determination to exclude Par (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Par's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Par may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

#### E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Par of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Par shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Par was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Par shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Par to pay Stipulated Penalties, such Stipulated Penalties shall

become due and payable 20 days after the ALJ issues such a decision unless Par requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Par was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Par had begun to take action to cure the material breach within that period; (ii) Par has pursued and is pursuing such action with due diligence; and (iii) Par provided to OIG within that period a reasonable timetable for curing the material breach and Par has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Par, only after a DAB decision in favor of OIG. Par's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Par upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Par may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Par shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Par, Par shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.



**XI. EFFECTIVE AND BINDING AGREEMENT**

Par and OIG agree as follows:

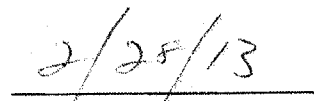
- A. This CIA shall be binding on the successors, assigns, and transferees of Par.
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA.
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.
- D. OIG may agree to a suspension of Par's obligations under this CIA based on a certification by Par that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If Par is relieved of its CIA obligations, Par will be required to notify OIG in writing at least 30 days in advance if Par plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.
- E. The undersigned Par signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.
- F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF PAR



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PAUL CAMPANELLI  
Chief Executive Officer  
Par Pharmaceutical Companies, Inc.



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DATE

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JOHN NASSIKAS, III  
Counsel  
Par Pharmaceutical Companies, Inc.

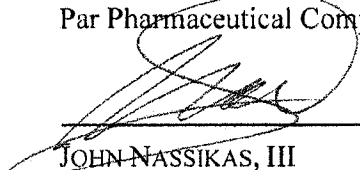
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DATE

ON BEHALF OF PAR

\_\_\_\_\_  
PAUL CAMPANELLI  
Chief Executive Officer  
Par Pharmaceutical Companies, Inc.

\_\_\_\_\_  
DATE

  
\_\_\_\_\_  
JOHN NASSIKAS, III  
Counsel  
Par Pharmaceutical Companies, Inc.

2/28/13  
\_\_\_\_\_  
DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Robert K. DeConti

ROBERT DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

3/1/13

DATE

Christina K. McGarvey

CHRISTINA K. MCGARVEY  
Senior Counsel  
Office of the Inspector General

3/4/13

DATE

Gy Lindquist

GREGORY LINDQUIST  
Associate Counsel  
Office of the Inspector General

3/4/13

DATE

Par Corporate Integrity Agreement



## **Appendix A to CIA for Par**

### **Independent Review Organization**

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

#### **A. IRO Engagement.**

Par shall engage an IRO (or IRO(s)) that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D, below. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by Par in response to a request by OIG, whichever is later, OIG will notify Par if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Par may continue to engage the IRO.

If Par engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Par shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Par at the request of OIG, whichever is later, OIG will notify Par if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Par may continue to engage the IRO.

#### **B. IRO Qualifications.**

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and have expertise in applicable Federal health care program and FDA requirements that relate to the Covered Functions. The assigned individuals shall also be experienced in risk identification and mitigation in relation to pharmaceutical product marketing and promotion. The assigned individuals also shall be knowledgeable about the general requirements of the Federal health care programs under which Par products are reimbursed;

2. assign individuals to design and select the samples for the IRO Transactions Reviews who are knowledgeable about appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each component of each IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;

3. if in doubt of the application of a particular Federal health care program or FDA requirement, request clarification from the appropriate authority (e.g., CMS or FDA);

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendices B and C to the CIA.

D. Independence and Objectivity.

The IRO must perform the IRO Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination.

1. *Par Termination of IRO.* If Par terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Par must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Par must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of the termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Par to engage a new



IRO in accordance with Paragraph A of this Appendix. Par must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Par to engage a new IRO, OIG shall notify Par of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Par may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Par prior to requiring Par to terminate the IRO. However, the final determination as to whether or not to require Par to engage a new IRO shall be made at the sole discretion of OIG.



## **APPENDIX B TO CIA FOR PAR**

### **INDEPENDENT REVIEW ORGANIZATION REVIEWS**

#### **I. Covered Functions Review, General Description**

As specified more fully below, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively, Par) shall retain an Independent Review Organization (IRO) (or IROs) to perform reviews (IRO Reviews) to assist Par in assessing and evaluating its systems, processes, policies, procedures, and practices related to certain of Par's Covered Functions. The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Par may engage, at its discretion, a single IRO to perform both components of the IRO Reviews provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Par's systems, processes, policies, and procedures relating to the Covered Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Par materially changes its systems, processes, policies, and procedures relating to the Covered Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

#### **II. IRO Systems Review**

##### **A. Description of Reviewed Policies and Procedures**

The Systems Review shall be a review of Par's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain of the Covered Functions. Where practical, Par personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo

review of the information gathered or activities undertaken by Par in accordance with the preceding sentence.

Specifically, the IRO shall review Par's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"). If Par does not conduct an activity described below during that Reporting Period, the IRO does not need to conduct a Systems Review of that activity.

- 1) Par's systems, processes, policies, and procedures applicable to the manner in which Par sales representatives and field personnel (including sales personnel and marketing personnel) and personnel from the Medical Affairs department handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (*i.e.*, off-label) uses of Government Reimbursed Products) and the dissemination of materials relating to the uses of these products. This review shall include:
  - a) the manner in which Par sales personnel and other field personnel handle requests for information about off-label uses of Government Reimbursed Products (*i.e.*, by referring all such requests to Medical Affairs personnel at Par);
  - b) the manner in which Medical Affairs personnel, including those at Par's headquarters, handle and respond to requests for information about off-label uses of Government Reimbursed Products (including tracking the requests and using pre-approved materials for purposes of responding to the request);
  - c) the form and content of information and materials related to Government Reimbursed Products disseminated to HCPs (as defined in section II.C.9 of the CIA), and health care institutions (HCIs), Payers, and formulary decision-makers by Par;
  - d) Par's systems, processes, policies, and procedures (including the Inquiries Database) to track requests to Medical Affairs for information about off-label uses of products and responses to those requests;

- e) the manner in which Par collects and supports information reported in any systems used to track and respond to requests to Medical Affairs for Government Reimbursed Product information, including its Inquiries Database;
  - f) the processes and procedures by which Medical Affairs, the Compliance Officer, or other appropriate individuals within Par identify situations in which it appears that off-label or other improper promotion may have occurred; and
  - g) Par's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;
- 2) Par's systems, processes, policies, and procedures applicable to the manner and circumstances under which its Medical Affairs personnel participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products and the role of the Medical Affairs personnel at such meetings or events;
- 3) Par's systems, processes, policies, and procedures relating to Par's internal review of promotional materials related to Government Reimbursed Products disseminated to HCPs, HCIs and Payers and individuals or entities (*e.g.*, PBMs) acting on behalf of HCPs, HCIs or government payers;
- 4) Par's systems, policies, processes and procedures relating to incentive compensation for Covered Persons who are prescriber-facing sales personnel and their direct managers, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Relevant Government Reimbursed Products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance. Par's systems, policies, and procedures shall be consistent with the Employee and Executive Incentive Compensation Restriction Program required under section III.H of the CIA. To the extent that Par establishes different methods of

compensation for different Relevant Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;

5) Par's systems, policies, processes and procedures relating to the Executive Financial Recoupment Program described in Section III.H of the CIA and in Appendix D;

6) Par's systems, processes, policies, and procedures relating to the development and review of Call Plans (as defined in Section III.B.2.h of the CIA) for Relevant Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the Call Plans based on expected utilization of Relevant Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;

7) Par's systems, processes, policies, and procedures relating to Sample Distribution Policies and Procedures (as defined in Section III.B.2.i of the CIA). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Par (including, separately, from Par sales representatives and other Par personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by Par through sales representatives or are distributed from a central location and the rationale for the manner of distribution;

8) Par's systems (including any centralized electronic systems), processes, policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;

9) Par's systems, processes, policies, and procedures relating to engagement of non-speaker related consultants or other fee-for-service arrangements entered into with HCPs or HCIs and all events and expenses associated with such activities;

10) Par's systems, processes, policies, and procedures relating to Par's funding, directly or indirectly, of Third Party Educational Activities (as

defined in Section II.C.8 of the CIA) and all events and expenses relating to such activities;

11) Par's systems, processes, policies, and procedures relating to the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter Compendia). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information, (e.g., any changes based on Par's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia). Par represents that it does not make any submissions to the Compendia. The review shall also assess Par's processes relating to Par's annual review of information in the Compendia about Par's Government Reimbursed Products when Par makes any submission of information during the Reporting Period to any Compendia and Par's review of all arrangements, processing fees, or other payments or financial support (if any) related to Government Reimbursed Products provided to any Compendia; and

12) the form and content of information and materials disseminated by Par to Payers and Payer subcontractors, e.g., PBMs, and Par's systems, policies, processes, and procedures relating to Par's internal review and approval of information and materials related to Government Reimbursed Products disseminated to Payers and Payer subcontractors by Par.

#### B. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of Par's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-12 above, including a general description of Par's control and accountability systems



(e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-12 above are made known or disseminated within Par;

4) a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products (including the Inquiries Database);

5) findings and supporting rationale regarding any weaknesses in Par's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

6) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

### III. IRO Transactions Review

As described more fully below in Sections III.A-F, the Transactions Review shall include: (1) a review of a sample of Inquiries reflected in the Inquiries Database; (2) a review of Par's Call Plans and Par's Call Plan review process; (3) a review of Sampling Events as defined below in Section III.C; (4) a review of records relating to a sample of the Payments that are reported by Par pursuant to Section III.O of the CIA; and (5) a review of up to four additional items identified by the OIG in accordance with Section III.E.1.b of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

#### A. Review of Inquiries and Inquiries Database

##### 1) Description of Inquiries Database

As set forth in Section III.B.2.e of the CIA, Par shall use a database to track information relating to requests for information received by Par about its Government Reimbursed Products (hereafter "Inquiries"). Specifically, Par shall document and record all Inquiries received from HCPs or HCIs regarding Government Reimbursed Products in a database(s) (the "Inquiries Database"). Par shall record in the Inquiries Database the following

information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of requesting HCP or HCI or other individual or entity; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label use for the product (on-label, off-label, or unable to determine); 6) nature/form of the response from Par (including a record of any materials provided in response to the request); and 7) the name of the Par representative who called on or interacted with the HCP, customer, or HCI, if known.

2) Internal Review of Inquiries Database

On a semi-annual basis, the Compliance Officer shall review the Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters ("Inquiry Report"). The Compliance Officer shall review the Inquiry Reports to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If the Compliance Officer, in consultation with other appropriate Par personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the Compliance Officer shall undertake a follow-up review of the Inquiry (Off-Label Review), make specific findings based on his/her Off-Label Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.J of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of at least 10 percent but not more than 50 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. Eighty percent of the Inquiries reviewed by the IRO shall be Inquiries for which Par conducted an Off-Label Review, and the remainder of the random sample shall be Inquiries for which Par did not conduct an Off-Label Review. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the Inquiries Database for each reviewed Inquiry; and
- b) For each Inquiry for which the Compliance Officer conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by Par based on the Off-Label Review findings.

**B. IRO Review of Par's Call Plans and Call Plan Review Process**

The IRO shall conduct a review and assessment of Par's review of its Call Plans for Relevant Government Reimbursed Products as set forth in Section III.B.2.h of the CIA. Par shall provide the IRO with: i) a list of Relevant Government Reimbursed Products promoted by Par during the Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) the Call Plans for each such product. Par shall also provide the IRO with information about the reviews of Call Plans that Par conducted during the relevant Reporting Period and any modifications to the Call Plans made as a result of Par's reviews.

For each Call Plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the Call Plan. For each Call Plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by Par in conducting its review and/or modifying the Call Plan. The IRO shall seek to determine whether Par followed its criteria and Policies and Procedures in reviewing and modifying the Call Plan.

The IRO shall note any instances in which it appears that the sampled HCPs or HCIs on a particular Call Plan are inconsistent with Par's criteria relating to the Call Plan and/or Par's Policies and Procedures. The IRO shall also note any instances in which it appears that Par failed to follow its criteria or Policies and Procedures.

**C. IRO Review of the Distribution of Samples of Par Relevant Government Reimbursed Products**

The IRO shall conduct a review and assessment of the distribution of samples of Relevant Government Reimbursed Products to HCPs and HCIs. Par shall provide the IRO with: i) a list of Relevant Government Reimbursed Products for which Par

distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) information about Par's Sample Distribution Policies and Procedures. Par shall also provide the IRO with information about the reviews of Sample Distribution Policies and Procedures that Par conducted during the Reporting Period as set forth in Section III.B.2.i of the CIA and any modifications to the Sample Distribution Policies and Procedures made as a result of Par's reviews.

For each Relevant Government Reimbursed Product for which Par distributed samples during the Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which Par provided samples of the product to HCPs or HCIs. Each such instance shall be known as a "Sampling Event."

For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI. The reviewed materials shall include materials about the following: 1) the quantity, dosage, and form of the Par product provided to the HCP or HCI; 2) the identity and type of medical specialty or clinical practice of the HCP or HCI; 3) which individual Par sales personnel or other Par personnel provided the sample to the HCP or HCI; and 4) the manner and mechanism through which the sample was requested (e.g., sample request form, letter, or call to Par).

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the Relevant Government Reimbursed Product approved by the FDA and whether the sample was distributed by an Par representative in a manner consistent with Par's sample distribution policy for the product(s) provided during the Sampling Event. To the extent that a sample was provided to an HCP or HCI by a Par representative other than a sales personnel, the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g., conversations with a Par sales representative, conversation with a Par representative at headquarters, independent research, or knowledge of the HCP or HCI).

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the Relevant Government Reimbursed Product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses

of the Relevant Government Reimbursed Product approved by the FDA. For each such situation, the IRO shall note the process followed by Par in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that Par failed to follow its Sample Distribution Policies and Procedures for the Relevant Government Reimbursed Product(s) provided during the Sampling Event.

D. IRO Review of Physician Payment Listings

1. Information Contained in Physician Payment Listings

For purposes of the IRO Review as set forth in this Section III.D, each annual listing of physicians and Related Entities who received Payments (as defined in Section III.O of the CIA) from Par shall be referred to as the "Physician Payment Listing" or "Listing." For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) physician's full name; ii) name of Related Entity (if applicable); iii) city and state of the physician's practice or the Related Entity; and (iv) the aggregate value of the Payment(s) in the preceding year(s).

For purposes of this IRO Review, the term "Control Documents" shall include all documents or electronic records associated with each Payment reflected in the Physician Payments Listing for a sampled physician and/or Related Entity. For example, the term "Control Documents" includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by field personnel or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2. Selection of Sample for Review

For each IRO Reporting Period, the OIG shall have the discretion to identify at least 10 percent but no more than 50 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO at least 90 days prior to the end of the Reporting Period of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select at least 10 percent but no more than 50 physicians and/or Related

Entities to be included in the review. If Par's Physician Payment Listing contains 10 or fewer physicians and/or Related Entities, the IRO shall consult with OIG regarding the number of physicians and/or Related Entities to review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in the Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

3. IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Par's policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the value of the Payments(s) reflected in the Control Documents; and
- d) Whether the Control Documents reflect that Par's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with Par's policies).

4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:



- i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
  - ii. the IRO cannot confirm that Par otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or
- b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Par's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Par has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that Par otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

#### E. IRO Review of Additional Items

As set forth in Section III.E.1.b of the CIA, for each Reporting Period, the OIG at its discretion may identify up to four additional items for the IRO to review (hereafter "Additional Items"). No later than 150 days prior to the end of the applicable Reporting Period, the OIG shall notify Par of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Par shall submit an audit work plan to the OIG for



approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Par's systems, processes, policies, and procedures based on its review of each Additional Item).

Par may propose to the OIG that its internal audit(s) be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Par's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Par's planned internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Par's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Par's request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Par shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of Par's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Par in its internal audits.

#### F. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

- 1) General Elements to Be Included in Report
  - a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;

- b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
- c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

2) Results to be Included in Report

The following results shall be included in each Transaction Review Report:

(Relating to the Review of Inquiries)

- a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
- b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the Inquiries Database;
- c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the Inquiries Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by Par as a result of the Compliance Officer's findings;
- d) the findings and supporting rationale regarding any weaknesses in Par's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;

- e) recommendations for improvement in Par's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Call Plan Reviews)

- f) a list of the Relevant Government Reimbursed Products promoted by Par during the Reporting Period and a summary of the FDA-approved uses for such products;
- g) for each Relevant Government Reimbursed Product which was promoted during the Reporting Period: i) a description of the criteria used by Par in developing or reviewing the Call Plans and for including or excluding specified types of HCPs or HCIs from the Call Plans; ii) a description of the review conducted by Par of the Call Plans and an indication of whether Par reviewed the Call Plans as required by Section III.B.2.h of the CIA; iii) a description of all instances for each Call Plan in which it appears that the HCPs and HCIs included on the Call Plan are inconsistent with Par's criteria relating to the Call Plan and/or Par's Policies and Procedures; and iv) a description of all instances in which it appears that Par failed to follow its criteria or Policies and Procedures relating to Call Plans or the review of the Call Plans;
- h) the findings and supporting rationale regarding any weaknesses in Par's systems, processes, policies, procedures, and practices relating to Par's Call Plans or the review of the Call Plans, if any;
- i) recommendations, if any, for changes in Par's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to Call Plans or the review of the Call Plans;

(Relating to the Sampling Event Reviews)

- j) for each Relevant Government Reimbursed Product distributed during the Reporting Period: i) a description of Sample Distribution Policies and Procedures (including whether sales representatives may provide samples for the product and, if so, to HCPs or HCIs of

which medical specialty or type of clinical practice a sales representative may provide samples); ii) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event was not consistent with the uses of the product approved by the FDA. This description shall include a description of the process followed by Par in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that Par failed to follow its Sample Distribution Policies and Procedures for the Relevant Government Reimbursed Product(s) provided during the Sampling Event;

- k) the findings and supporting rationale regarding any weaknesses in Par's systems, processes, policies, procedures, and practices relating to Par's distribution of samples of Relevant Government Reimbursed Products, if any;
- l) recommendations, if any, for changes in Par's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples;

(Relating to the Physician Payment Listing Reviews)

- m) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;
- n) for each sampled physician or Related Entity, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Par policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that Par's policies were followed in connection with the underlying activity reflected in the document

(e.g., all required approvals were obtained); and (v) disciplinary action was undertaken in those instances in which Par policies were not followed;

- o) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;
- p) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Additional Items)

- q) for each Additional Item reviewed, a description of the review conducted;
- r) for each Additional Item reviewed, the IRO's findings based on its review;
- s) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Par's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
- t) for each Additional Item reviewed, recommendations, if any, for changes in Par's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.



## **Appendix C to CIA for Par**

### **IRO Reviews of Par's Enterprise Risk Management Process**

#### **I. General Description of the Enterprise Risk Management Process**

Prior to Effective Date of the CIA, Par implemented an Enterprise Risk Management (ERM) process. Par represents that it designed the ERM process to generate a strategic review assessment for each of Par's functional operating areas and business units. Par's Enterprise Risk Management Committee performs the strategic risk assessment. Par shall modify the ERM process as necessary to assess risks associated with the marketing and promotion of each of its Government Reimbursed Products. Based on the outcomes of the risk identification and assessment process, Par legal, compliance and other personnel shall centrally develop and implement specific plans designed to mitigate or reduce the identified risks. Par shall develop a customized risk mitigation plan for each Relevant Government Reimbursed Product.

##### *1. Risk Identification and Evaluation*

As part of the ERM process, Par will solicit risk information from key operating areas: (i) Strativa business; (ii) sales and marketing; (iii) regulatory affairs; (iv) quality assurance/quality control; (v) research and development; (vi) legal; (vii) audit; and (viii) the Compliance Officer.

Based on inputs from these sources, Par's Enterprise Risk Management Committee will produce a relative risk ranking report (Risk Evaluation Report). The Risk Evaluation Report will be presented to the Compliance Committee with recommendations regarding which products may require enhanced risk mitigation plans and a copy shall be provided to the Board of Directors.

The Risk Evaluation Report will also be used by the Compliance Officer to inform the risk-based selection of products as required by the Field Force Monitoring Program described in CIA Section III.L.

##### *2. Risk Mitigation Plans*

Risk Mitigation Plans (RMPs) will be completed annually for all Par Relevant Government Reimbursed Products. All RMPs will outline standard risk mitigation activities that will be performed and tracked for each Par Relevant Government Reimbursed Product, regardless of the product's relative risk ranking (Standard RMPs). Standard risk mitigation activities will consist of the monitoring activities to be conducted for each Par Relevant Government Reimbursed Product in the upcoming year, such as ride-alongs with sales personnel, sampling, verbatim reviews, monitoring of speaker programs, speaker training, advisory boards, and medical information requests.



Based on the Risk Evaluation Report, Relevant Government Reimbursed Products may be selected for Enhanced RMPs by the Compliance Committee or Compliance Officer. These RMPs will include enhanced risk mitigation activities, in addition to the standard activities (Enhanced RMPs). Enhanced RMPs will consist of activities tailored to the risks identified during the risk ranking process. For example, such activities may include increased compliance messaging, modifications to or limitations of promotional programs, or enhanced training requirements.

All RMPs (whether Standard or Enhanced) will be developed jointly by the Compliance Officer and the applicable department on an annual basis. Each RMP will specify the: (i) risk monitoring activities; (ii) metrics by which risk monitoring results will be evaluated and/or measured; (iii) risk mitigation action items, if necessary; (iv) metrics by which risk mitigation activities and results will be evaluated and/or measured; (v) responsible individual(s); and (vi) expected date(s) of monitoring and/or action item completion.

### 3. *Risk Mitigation Plan Tracking*

RMP activities (including risk monitoring activities, risk mitigation activities, and risk mitigation action items) will be tracked by the Compliance Officer. The Compliance Officer shall report on RMP activities specified above on at least a quarterly basis to the Board and to the Compliance Committee.

## II. Enterprise Risk Management Review, General Description

A. As specified more fully below, Par shall retain an IRO to assist Par in assessing and evaluating its systems, processes, policies, procedures, and practices relating to the Enterprise Risk Management Review (ERM Review) as modified by Par to identify the risks associated with marketing and promotion of Government Reimbursed Products. The ERM Review shall consist of two components - a systems review (ERM Systems Review) and a transactions review (ERM Transactions Review) as described more fully below. Par may engage, at its discretion, a single IRO to perform both components of the ERM Review provided that the entity has the necessary expertise and capabilities to perform both.

B. If there are no material changes in Par's systems, processes, policies, and procedures relating to Risk Mitigation Program, the IRO shall perform the ERM Systems Review for the first and fourth Reporting Periods. If Par materially changes its systems, processes, policies, and procedures relating to the ERM Program, the IRO shall perform an ERM Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods. The additional ERM Systems Review(s) shall consist of: (1) an identification of the material changes; (2) an assessment of whether other systems, processes, policies, and

procedures previously reported did not materially change; and (3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the ERM Transactions Review for the first through fifth Reporting Periods of the CIA.

### III. ERM Systems Review

#### A. The ERM Systems review shall consist of the following:

1. A review of the processes by which Par develops and evaluates Risk Evaluation Reports and develops Standard and Enhanced RMPs, including the sources of information (e.g., the individual personnel, departments or functional areas, and/or any systems involved) used to compile the Reports and RMPs; the types of underlying data and information that are considered or evaluated during the development of the Risk Evaluation Reports and the RMPs; and the timing for development of Risk Evaluation Reports and the RMPs;
2. An assessment of whether, in developing the Risk Evaluation Reports and the RMPs: i) additional or different sources of information; ii) additional or different types of data or information; and iii) additional or different timing cycles should be utilized;
3. A review of the experience and background of the individuals responsible for development of the RMPs and an assessment of the completeness and appropriateness of the training, policies, procedures, standard operating procedures, and guidance such individuals receive regarding the development of the RMPs;
4. An assessment of whether the standard risk mitigation activities (monitoring activities) included in RMPs are designed to: (i) adequately monitor all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) ensure that the activity associated with an identified risk does not occur in the future;
5. An assessment of whether standard risk mitigation activities (monitoring activities) that may be included in RMPs should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; (iii) tracked and reviewed more frequently than

prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed;

6. An assessment of whether enhanced risk mitigation activities and risk mitigation action items (and options for such activities) included in Enhanced RMPs are designed to: (i) adequately address all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) ensure that the activity associated with an identified risk does not occur in the future;
7. An assessment of whether enhanced risk mitigation activities that may be included in RMPs should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed; and
8. A review of the systems, policies, procedures, and processes by which Par tracks and manages RMP activities and an assessment of whether the systems, policies, procedures and processes ensure that the RMPs are appropriately implemented (including by identifying individuals responsible for the follow-up or action items).

B. The IRO shall prepare a report based upon each ERM Systems Review performed (ERM System Review Report). The ERM Systems Review Report will include the IRO's findings, recommendations, observations, and comments on items 1-8 above and, to the extent not otherwise addressed, an assessment of the following: (i) whether the Risk Evaluation Reports and RMPs identify and prioritize relevant risks; (ii) whether the risk monitoring activities, risk mitigation activities and any risk mitigation action items identified in RMPs address identified risks; (iii) whether sufficient controls exist to ensure that all risk mitigation steps (including monitoring activities and risk mitigation activities) are completed in accordance with the RMPs; iv) whether the options for risk monitoring activities and risk mitigation activities identified in the RMPs address and potentially mitigate identified risks; and (v) whether sufficient controls exist to ensure that all agreed-upon risk monitoring activities and risk mitigation activities are completed in accordance with the RMPs.

#### IV. ERM Transactions Review

A. At least thirty (30) days prior to the end of the first through fifth Reporting Periods, Par shall submit to OIG a list of all Par Relevant Government Reimbursed

Products for which RMPs were developed. Par shall notify the OIG about which products had Standard RMPs and which products had Enhanced RMPs. Prior to the end of the applicable Reporting Period, OIG shall select up to 3 Par Relevant Government Reimbursed Products (each a "Selected Product" and together the "Selected Products") to be reviewed in connection with the ERM Transactions Review.

B. For each Reporting Period and for each Selected Product, the IRO shall conduct a review of: i) the applicable Risk Evaluation Report entry and RMP; ii) documents and materials related to the development of the RMP; and iii) documents and materials relating to the implementation of the RMP. The IRO shall also interview the individual(s) responsible for the development of the RMP and the individual(s) responsible for the implementation of the risk monitoring and risk mitigation activities specified in the RMP.

The objective of the IRO shall be to: (i) understand the processes followed by Par in developing the RMP for each Selected Product, including the underlying bases for Par's decision to develop either a Standard RMP or an Enhanced RMP for the Selected Product; (ii) determine whether, based on the information contained in the Risk Evaluation Report, an appropriate RMP (including as to the included risk monitoring activities, risk mitigation activities, and risk mitigation action items) was developed for the Selected Product; and (iii) assess Par's implementation and tracking of the implementation of the RMP for the Selected Product.

C. The IRO will prepare a report based on each ERM Transactions Review performed (ERM Transaction Review Report). The Transactions Review Report shall include the following:

1. an identification of the Selected Products and a description of the documents and information reviewed in connection with each Selected Product, including a description of whether the RMP for each Selected Product was a Standard RMP or an Enhanced RMP;
2. for each Selected Product, a description of: i) the process followed in developing the RMP; and ii) the types of identified risks associated with the Selected Product;
3. for each Selected Product, an assessment of whether it was appropriate for Par to develop, as applicable, an Enhanced or a Standard, RMP for the product;

4. for each Selected Product, an assessment of whether, based on the information contained in the Risk Evaluation Report, an appropriate RMP was developed for the Selected Product;
5. for each Selected Product, a description of the expertise and backgrounds of the individuals who were responsible for the development of the RMP;
6. for each Selected Product, a description of the following items set forth in the RMP: (i) risk monitoring activities; (ii) metrics by which the risk monitoring activities and results will be evaluated and/or measured; (iii) risk mitigation activities, including any risk mitigation action items; (iv) metrics by which the risk mitigation activities and results will be evaluated and/or measured; (v) responsible individual(s); (vi) expected date(s) of completion for each risk monitoring activity and risk mitigation activity; and (vii) if the RMP did not specify each of the items set forth above, a description of any deficiencies;
7. for each Selected Product, a description of whether risk monitoring activities specified in the RMP were implemented and tracked in accordance with the RMP and Par's policies and procedures, and a description of any deficiencies;
8. for each Selected Product, a description of whether risk mitigation activities (including any action items) specified in the RMP were implemented and tracked in accordance with the RMP and Par's policies and procedures, and a description of any deficiencies;
9. for each Selected Product a description of: (i) any recommendations made by the IRO regarding the RMP or any risk monitoring activities and risk mitigation activities included in the RMP; (ii) whether, and in what manner, Par implemented the recommendations from the IRO; and (iii) if Par did not implement the IRO recommendations, a description of the rationale for Par's decision not to implement the recommendations; and
10. the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in Par's systems, processes, policies, procedures, and practices relating to the ERM program, if any; and recommendations, if any, for changes in Par's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies

uncovered during the Transactions Review with respect to the ERM program.





**Appendix D to CIA for Par**  
**Executive Financial Recoupment Program**

**Executive Financial Recoupment Program.** Through its Existing Commitments and the New Commitments to be implemented, Par shall establish and maintain throughout the term of the CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay for an executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). Par's Existing Commitments and New Commitments are described below. This financial recoupment program shall apply to Covered Executives, as defined below in Paragraph B, who are either current Par employees or who are former Par employees at the time of a Recoupment Determination.

(A) **Existing Commitments.** Except as may be required in connection with controlling local law or as may be required in connection with Par's preexisting contractual obligations if they were made before January 1, 2013, the annual cash bonus for each Par employee (including each executive) is at risk of forfeiture in the event of the employee's discharge for cause. Except as may be required in connection with controlling local law, in the event grounds exist for discharge for cause of any Par employee worldwide, Par also has reserved the right and full discretion to void and forfeit any unvested or unexercised stock options, stock appreciation right, and similar equity plans (collectively, "Equity Awards"). If Par discovers any employee misconduct that would implicate the forfeitures described in this paragraph by a Covered Executive (collectively, "Existing Commitments"), it shall evaluate the situation and make a determination about whether any forfeiture, and the terms of such forfeiture, shall be implemented.

(B) **New Commitments.** Within 120 days after the Effective Date of the CIA, Par shall modify and supplement its annual bonus plan (and any employment agreements, as appropriate) by imposing the following eligibility and repayment conditions on future bonuses and Equity Awards and making the additional remedies discussed below (collectively, "New Commitments") applicable to all senior Par executives at the level of Vice President or above (collectively, "Covered Executives"). Par shall implement Policies and Procedures and, as necessary, shall modify contracts with Covered Executives so that beginning in calendar year 2014 the annual bonuses and Equity Awards may be recouped if a Triggering Event occurs, as defined in Section C below, and the Recoupment Committee makes a Recoupment Determination. The New Commitments shall apply prospectively to Covered Executives beginning with the calendar year 2014 bonus plan and Equity Award years.

(i) **Executive Bonus Eligibility and Repayment Conditions.** Par shall implement an eligibility and repayment condition on annual bonuses that shall be

designed to survive both the payment of the bonus and the separation of a Covered Executive's employment. This will allow Par, as a consequence of a Triggering Event as defined below in Paragraph C, to pursue repayment from the Covered Executive of all or any portion of the bonus monies paid to the Covered Executive. To the extent permitted by controlling law, these bonus eligibility and repayment conditions will survive the payment of the Covered Executive's bonus and the separation of the Covered Executive's employment for a period of 3 years from the payment of the bonus for the plan year. If payment of any portion of a bonus is deferred on a mandatory or voluntary basis, the 3 year period shall be measured from the date the bonus would have been paid in the absence of deferral.

Consistent with a Recoupment Determination, as defined below in Paragraph D, Par shall endeavor to collect repayment of any bonus from the Covered Executive through reasonable and appropriate means according to the terms of its bonus plan (or executive contract, as the case may be), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary to collect the repayment, Par shall file suit against the Covered Executive unless good cause exists not to do so. For purposes of the Executive Financial Recoupment Program, good cause shall include, but not be limited to, a financial inability on the part of the Covered Executive to repay any recoupment amount or Par's inability to bring such a suit under the controlling law of the relevant jurisdiction.

(ii) **Equity Awards and Repayment Conditions.** Par shall implement an eligibility and repayment condition on Par's deferred or unvested Equity Awards designed to survive the separation of a Covered Executive's employment. More specifically, to the extent necessary, Par shall implement an eligibility and repayment condition on Par's deferred or unvested Equity Awards in order to clarify that, as a consequence of a Triggering Event, Par may pursue repayment by a Covered Executive who is a former employee of all or any portion of the last 3 years' worth of any Equity Awards that became vested during the 3 years preceding the Recoupment Determination.

To the extent permitted by controlling law, these eligibility and repayment conditions shall survive vesting and payment for a period of 3 years from the Covered Executive's employment termination date. In addition, Par shall amend the vesting schedule of Par's deferred or unvested Equity Awards (but only as to awards made in 2014 and later Equity Award Years) so that Covered Executives who are "good leavers" (e.g., terminating employment due to retirement, death or disability) will no longer vest in, nor receive a distribution of, any unvested Equity Awards immediately following termination of employment; rather, such deferred or unvested Equity Awards will only vest and be distributable after the first anniversary of the Covered Executive's termination of employment. Consistent with a Recoupment Determination, Par shall collect repayment of these deferred or unvested Equity Awards from the Covered Executive to the extent permitted by controlling law of the jurisdiction in which the Covered Executive works. If

necessary to collect the repayment, Par shall file suit against the Covered Executive unless good cause exists not to do so.

(iii) **Tolling Remedy.** To the extent permitting by controlling law, for the 6 years during which the bonus and Equity Award eligibility and repayment conditions exist, if Par reasonably anticipates that a Triggering Event has occurred pursuant to Paragraph C, and Par has recoupment rights remaining under Paragraphs B(i) and B(ii), Par shall have the right to notify the Covered Executive that those rights shall be tolled and thereby extended for an additional 6 years or until the Recoupment Committee determines that a Triggering Event has not occurred, whichever is earlier, to the extent permitted by controlling law of the relevant jurisdiction.

(iv) **Additional Remedies.** If, after expiration of the time period specified in Paragraphs B(i)-(iii) above, the Recoupment Committee determines that a Triggering Event occurred, Par shall make a determination as to whether to pursue available remedies (*e.g.*, filing suit against the Covered Executive) existing under statute or common law to the extent available.

(C) **Definition of Triggering Events.** The eligibility and repayment conditions described above shall be triggered upon a Recoupment Determination that finds:

(i) significant misconduct (*e.g.*, violation of a significant Par policy, or regulation, or law) by the Covered Executive that, if discovered prior to payment, would have made the Covered Executive ineligible for an annual bonus, bonus deferral, or other deferred or unvested Equity Awards in that plan year or subsequent plan years; or

(ii) significant misconduct by subordinate employees in the business unit over which the Covered Executive had responsibility that does not constitute an isolated occurrence and which the Covered Executive knew or should have known was occurring that, if discovered prior to payment, would have made the Covered Executive and/or employees in question ineligible for an annual bonus, bonus deferral or other deferred or unvested Equity Awards in that plan year or subsequent plan years.

(D) **Administration of Recoupment Program.** Par shall engage in a standardized, formal process to determine, in its sole discretion, whether a Triggering Event has occurred, and, if so, the extent of bonus monies, deferred or unvested Equity Awards, and deferred compensation that will be subject to repayment or forfeiture by the Covered Executive, and the most appropriate method for securing recoupment of relevant monies previously paid to a Covered Executive. The findings and conclusions resulting from this process shall be referred to as the "Recoupment Determination".

(i) **Initiation.** Par shall initiate the Recoupment Determination process upon: (1) discovery of potential significant misconduct that may rise to the level of a

Triggering Event, or (2) written notification by a United States federal government agency to Par's Compliance Officer of a situation that may rise to the level of a Triggering Event and either occurred in the United States or gives rise to liability relating to Federal healthcare programs. This written notification shall either identify the Covered Executive(s) potentially at issue or provide information (*e.g.*, a description of the alleged misconduct and the applicable time period) to allow Par to identify the Covered Executive.

(ii) **Recoupment Committee.** The Recoupment Determination shall be made by a committee of senior executives headed by Par's Compliance Officer (Recoupment Committee). A senior executive shall not participate in the Recoupment Committee while the subject of a Recoupment Determination. If a Recoupment Determination involves the President; Chief Executive Officer; Chief Financial Officer; Compliance Officer; Senior Vice President of Sales, Strativa; Senior Vice President of Sales, Par Pharmaceutical; and Vice President, Regulatory Affairs, a Recoupment Determination for such individual shall be subject to ratification by the Board of Directors (or appropriate committee thereof) of Par. Par's Board of Directors may, in its discretion, provide that the Recoupment Committee shall consist exclusively of non-employee members of the Board of Directors if at least three such non-employee members are appointed to serve as the Recoupment Committee. Par shall notify OIG in writing within 15 days of any change in the composition of the Recoupment Committee with an explanation for the change.

(iii) **Timeline for Recoupment Determination Process.** Par shall initiate the Recoupment Determination process within 30 days after discovery by Par or notification, pursuant to Paragraph D(i), of a potential Triggering Event. Absent extraordinary reasons, Par shall reach a Recoupment Determination within 90 days after initiation of the determination process.

In connection with making its Recoupment Determination, the Recoupment Committee or appropriate Delegate (as defined below) pursuant to implementing policies and procedures shall: i) undertake an appropriate and substantive review or investigation of the facts and circumstances associated with the Triggering Event or any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) make written findings regarding the facts and circumstances associated with the Triggering Event and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; and iii) set forth in writing its determinations (and the rationale for such determinations) about: 1) whether a Triggering Event occurred; 2) the extent of bonus monies, or deferred or unvested Equity Awards that will be subject to forfeiture and/or repayment by the Covered Executive; 3) the means that will be followed to implement the forfeiture and/or secure the recoupment of performance pay from the Covered Executive; and 4) the timetables under which Par will implement the forfeiture and/or attempt to recoup the performance pay. For purposes of

this paragraph, a “Delegate” shall refer to the Par personnel to whom the Recoupment Committee has delegated one or more of its required tasks in furtherance of the Executive Financial Recoupment Program.

**(E) Reporting.** The Recoupment Committee shall provide annual reports to the Board of Directors (or an appropriate committee thereof) of Par about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) a description of any Recoupment Determinations made during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the means for collecting any recoupment and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Recoupment Determinations that were not fully completed in prior years.

The Recoupment Committee shall also provide annual reports to the OIG about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) a summary description of any Recoupment Determinations made during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the method for collecting any recoupment, and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Recoupment Determinations that were not fully completed in prior years. Par shall provide OIG with additional information regarding any Recoupment Determination upon OIG’s request.


Par commits, to the extent permitted by controlling local law, to maintaining all of the forfeiture and recoupment commitments set forth in Paragraphs A-E above for at least the duration of the CIA, absent agreement otherwise with the OIG.



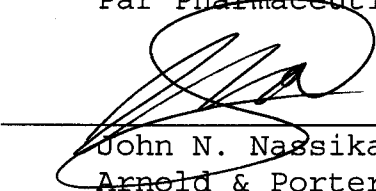
Acknowledgement of Plea Agreement

The Board of Directors (the "Board") of Par Pharmaceutical Companies, Inc. ("Par") has authorized me to execute this Plea Agreement on behalf of Par, and to take all such action as may be necessary to effectuate this Plea Agreement. The Board has reviewed this Plea Agreement, the related Criminal Information, and the related Civil Settlement Agreements, including all attachments, in their entirety and have discussed them fully in consultation with Par's attorneys. The Board acknowledges that these documents set forth Par's agreement with the United States fully. The Board further states that no additional promises or representations have been made to Par by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement and the Civil Settlement Agreements.

Dated: 3/4/13

  
\_\_\_\_\_  
Paul V. Campanelli  
Chief Executive Officer  
Par Pharmaceutical Companies, Inc.

Dated: 3/4/13

  
\_\_\_\_\_  
John N. Nassikas  
Arnold & Porter LLP  
Counsel for Par Pharmaceutical  
Companies, Inc and Par  
Pharmaceutical, Inc.





Certified Copy of Corporate Resolution

Upon motion duly made, seconded, and unanimously carried by the affirmative vote of all the Directors present, the undersigned, being all the members of the Board of Directors (the "Board") of Par Pharmaceutical Companies, Inc. ("Par"), hereby consented to and adopted the following resolutions:

WHEREAS, Par has been engaged in discussions with the United States Attorney's Office for the District of New Jersey (the "Office") in connection with an investigation being conducted by that Office regarding Par's marketing and promotional practices;

WHEREAS, the Board of Directors of Par has reviewed, with outside counsel, the Criminal Information and Civil Settlement Agreements related to that investigation;

WHEREAS, the Board of Directors of Par consents to resolution of these discussions by authorizing Par to plead guilty and enter into a plea agreement that the Par Board of Directors has reviewed with outside counsel, relating to the investigation conducted by the U.S. Attorney's Office for the District of New Jersey;

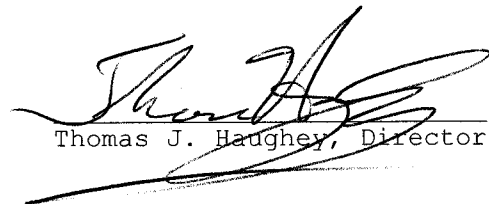
WHEREAS, the Board acknowledges that the aforementioned documents set forth Par's agreement with the United States fully, and that no additional promises or representations have been made to Par by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement and the attached Civil Settlement Agreements;

NOW THEREFORE, BE IT RESOLVED that Paul V. Campanelli, Par's Chief Executive Officer, be, and hereby is, authorized to execute the Plea Agreement on behalf of Par substantially in the same form as reviewed by Par Board of Directors at this meeting, and attached hereto as Attachment A.

Dated: March 4, 2013

  
Paul V. Campanelli, Director

  
Michael A. Tropiano, Director

  
Thomas J. Haughey, Director